

EXAMINING THERAPEUTIC ULTRASOUND MANUFACTURER BRANDS, MODELS,  
AND COMMON TREATMENT PARAMETERS AMONGST CLINICALLY PRACTICING  
ATHLETIC TRAINERS

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**Title**

EXAMINING THERAPEUTIC ULTRASOUND MANUFACTURER  
BRANDS, MODELS, AND COMMON TREATMENT PARAMETERS  
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## ABSTRACT

**Context:** Textbook parameters for thermal ultrasound are based on research using the Omnisound 3000 unit. No study has been performed to observe common brands of ultrasound (US) units available to athletic trainers (ATs), or the US parameters they commonly use.

**Objective:** Determine commonly reported US units and heating parameters used by ATs.

**Design:** Digital survey. **Setting:** Online survey database – Qualtrics. **Participants:** 21

responding ATs (mean  $12.5 \pm 10.6$  years ATC) **Results:** Chattanooga brand is the most available brand US unit by respondents. Respondent parameters tended to reach 1 and 2°C heating thresholds, but mostly failed to achieve 4°C threshold. Parameters did not differ between more experienced ( $\geq 10$  years ATC) and less experienced ATCs ( $\leq 10$  Years ATC). **Conclusions:**

Parameter guidelines need to be updated for clinically effective US use. **Key words:** therapeutic ultrasound, heating rates, parameters.

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## **DEDICATION**

I dedicate this research to my entire family, who all showed their tremendous love and support for me in all my academic endeavors. I especially thank my immediate family; Marc, Julie, Steve, and Tim, for all their emotional and financial support while I was away. And finally, to all my close friends from back home, and new friends from North Dakota - thank you all so much for your incredible love and support.

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## CHAPTER I. INTRODUCTION

Therapeutic Ultrasound (US) has been amply used since 1955 as a therapeutic modality in the treatment of a variety of conditions.<sup>3</sup> The use of therapeutic US has been demonstrated to provide beneficial effects on function and global pain reduction regarding musculoskeletal pain and injury. According to researchers,<sup>7,11,13</sup> therapeutic US as a technique in physical medicine has remained frequent among clinicians across the globe. Research indicates clinicians often select US treatments to treat soft tissue inflammation, decrease pain and swelling, increase tissue extensibility, and enhance scar tissue remodeling.<sup>11</sup> Increasing tissue temperature to certain levels via US is found to achieve therapeutic effects during treatment. An increase of 1°C, or mild heating, is applied either for treatment of minor inflammation or to accelerate metabolic rate and the total healing process.<sup>16,18</sup> Moderate heating, a 2-3°C increase, is used to treat muscle spasm and pain, increase blood flow, and reduce chronic inflammation.<sup>16,18</sup> A 4°C or greater increase, or vigorous heating, allows for increased tissue extensibility, reduction of scar tissue, and inhibition of sympathetic activity.<sup>16,18</sup>

Heating tissue to a desired temperature requires the clinician to input treatment parameters such as frequency, intensity, mode, and treatment duration into the US unit. Tissue heating rates and parameter guidelines of therapeutic US are commonly taught to clinicians based off research conducted by Draper et al,<sup>18</sup> who established heating rates commonly seen in therapeutic modality textbooks.<sup>16,18</sup> Draper et al<sup>18</sup> used the Omnisound 3000™; however, a variety of different manufacturers produce US units available for use by clinicians. Research is beginning to emerge on discrepancies of tissue heating rates in comparison of US units. In 2003, Merrick et al<sup>32</sup> examined Omnisound, Dynatron, and Excel US units and found only the Omnisound heated tissue to the vigorous heating threshold of 4°C, even though all parameters

between units remained identical. More recently, Gange et al<sup>35</sup> further inspected tissue heating rates associated with the Dynatron Solaris<sup>®</sup> US machine and found rates to be much slower than textbook heating recommendations. An unpublished thesis from Smith et al<sup>42</sup> observed heating rates from a Chattanooga Intellect Legend XT US unit which also differed from current textbook recommendations. Currently, little research exists on the availability of US manufacturer brands and models among practicing athletic trainers (ATs), or what common parameters of US are commonly used in treatment.

### **1.1. Statement of the Problem**

Athletic trainers and other health care clinicians rely on evidence-based practice to guide clinical decisions, including US modality application. While studies have been performed to measure resultant tissue temperatures of US treatments with several units,<sup>1,3,5,25-32,34-35</sup> little research exists on the availability of specific US units or parameters of US used by ATs clinically.

### **1.2. Purpose of the Study**

The purpose of this study is to examine the commonly used brands and models of US units used by ATs currently practicing clinically, as well as inquire about common US parameters ATs use to treat common conditions and pathology.

### **1.3. Research Questions**

1. What brands and models of therapeutic US units are most commonly available for use by clinical ATs?
2. What brands of therapeutic US units are most used by clinical ATs?
3. What are the most common thermal US parameters used by ATs clinically?

#### 1.4. Definition of Terms

*Absorption:* The process of a medium collecting thermal energy and changing it to kinetic energy.<sup>16</sup>

*Attenuation:* A decrease in the intensity of a wave due to the absorption, reflection, and refraction of energy.<sup>16,18</sup>

*Cavitation:* The formation of gas-filled bubbles that cause pressure changes in tissue fluids during US application.<sup>16,18</sup>

*Clinician:* a person qualified in the clinical practice of medicine, psychiatry, or psychology as distinguished from one specializing in laboratory or research techniques or in theory.<sup>43</sup>

*Contraindications:* Situations in which a modality is inadvisable or should not be used.<sup>16,18</sup>

*Coupling Medium:* A substance that facilitates the transmission of US energy by decreasing impedance at the air-skin interface.<sup>18</sup>

*Frequency:* The rate of passage of crests on a waveform, expressed as cycles per seconds or hertz (Hz).<sup>18</sup>

*Intensity:* A measure of the rate at which energy is being delivered per unit area.<sup>18</sup>

*Microstreaming:* The localized flow of fluids as a result of cavitation within tissues.<sup>16</sup>

*Therapeutic Ultrasound:* The application of ultrasonic energy on biological tissues to produce physiological changes.<sup>6</sup>

*Transducer:* A device that converts variations in a physical quantity (such as pressure or brightness) into an electrical signal, or vice versa. In the case of US, the device changes electrical

energy into acoustic energy. It is also known as the applicator or sound head that is moved on the treatment surface.<sup>18</sup>

*Treatment Parameters:* Settings that are utilized for a specific goal for US treatment including time, intensity and frequency.<sup>12</sup>

*Ultrasound Waves:* Mechanical vibrations like sound waves but with a frequency beyond the range of the human hearing.<sup>36</sup>

### **1.5. Importance of the Study**

There is currently no published literature on the availability of specific US brands or models used among clinically practicing ATs. Additionally, while temperature thresholds for mild, moderate, and vigorous heating are defined in modality textbooks<sup>16</sup> and literature-based US heating rates are taught to ATs,<sup>16,18</sup> no published research is available regarding US parameters commonly used by practicing ATs. It is essential to observe the common units and parameters used by ATs to further examine their clinical effectiveness and to guide future evidence-based practice for therapeutic US.

### **1.6. Limitations of the Study**

1. The digital questionnaire used in this study was developed by the primary and co-investigator, and not based on any previous criterion.
2. A healthy response rate from participants is required to effectively utilize and examine the data collected.

### **1.7. Delimitations of the Study**

1. The population of clinical ATs were selected randomly through the NATA Survey Research Center.
2. All subjects had 4 weeks to respond to the questionnaire.

3. All subjects were reminded for their participation in the questionnaire 2 weeks into the response period.

## **CHAPTER II. LITERATURE REVIEW**

The purpose of this study is to examine the commonly used brands and models of US units used by ATs currently practicing clinically, as well as inquire about common US parameters ATs use to treat common conditions and pathology. The following research questions were examined: 1.) What brands and models of therapeutic US units are most commonly available for use by clinical ATs? 2.) What brands of therapeutic US units are most used by clinical ATs? 3.) What are the most common thermal US parameters used by ATs clinically? This literature review is organized into the following areas: properties of US treatment, biomechanisms of therapeutic US, prevalence of US use, US treatment parameters, and variation among US units by manufacturer.

Tissue heating rates of therapeutic US commonly taught to clinicians are built on research conducted by Draper et al<sup>2</sup> who established heating rates using the Omnisound 3000™. Draper et al's published heating rates are still frequently observed in modern therapeutic modalities textbooks.<sup>2,18</sup> However, the capability of different brands and models of US machines to heat tissue is sparsely researched, despite the wide variety of different brands available for use by clinicians. To better examine and critique the current understanding of US parameters and how clinical guidelines have been established, a basic knowledge of US treatment properties and parameters must be reviewed.

### **2.1. Properties of Ultrasound Treatment**

#### **2.1.1. US Waves**

Ultrasound (US) waves are acoustic waves that function at a higher-level frequency than humans are capable of hearing. Therapeutic US ranges from 750,000 to 3 million vibrations per second. The human ear can only hear sound waves that vibrate between 16,000 and 20,000 times

per second,<sup>2</sup> hence the name US. Ultrasound waves, like any other type of acoustic wave, pass energy via vibrations between the molecules in whichever medium they are traveling through. Therapeutic US waves are less divergent than sound waves, and the energy they channel is concentrated to a limited area.

#### ***2.1.1.1. Ultrasound Wave Generation***

Ultrasound was originally introduced as a therapeutic modality to provide an alternative to shortwave diathermy and to compete with other forms of thermal modalities.<sup>6</sup> The acoustic properties of US set it apart from other thermal modalities. It is important to understand the mechanisms by which US waves are generated from the unit and how this process differs from electromagnetic modalities.

Generation of US waves stem from electric polarization produced by the expansion and contraction of a ceramic crystal by an alternating current located within the US transducer. Ultrasound wave creation begins with the production of alternating electrical energy by the generator within the unit. The alternating current produced is transmitted over the crystal. The crystal contracts and creates a voltage, which is known as the direct piezoelectric effect. Then, the crystal expands and inverts the voltage polarity, referred to as the reverse piezoelectric effect.<sup>18</sup> These events create high-frequency sound waves which are emitted from the US transducer. Thus, the electrical energy produced by the generator is converted to acoustic energy by crystal deformation. The properties of the electrical voltage produced by the generator, and therefore the subsequent US waves produced, can be altered by adjusting parameters on the unit's control panel.



### ***2.1.1.2. Propagation of US Waves Through Tissue***

Ultrasound waves require molecular interaction and transfer of vibration to adjacent molecules to propagate through a medium. They achieve this interaction in two ways, longitudinally or transversely, depending on the state of matter the wave is traveling through.<sup>18</sup> Longitudinal propagation of waves occurs in both solids and liquids and involves molecules vibrating along the direction in which the wave travels. Longitudinal waves contain areas of high molecular density and areas of low molecular density called compressions and rarefactions, respectively.<sup>18</sup> Transverse propagation of waves occurs in solids only and is characterized by molecules vibrating in a direction perpendicular to the direction in which the wave travels. In human soft tissue, US waves travel longitudinally until they encounter a solid medium such as bone, which causes US waves to be reflected as transverse waves.<sup>18</sup>

Transmission of a wave is defined as the act of the wave propagating through a material. As US waves are transmitted through a medium, a decrease in energy occurs and is termed attenuation. Attenuation of US waves results from absorption, reflection, and refraction of the wave.<sup>18</sup> When ultrasonic energy is absorbed, it is converted into kinetic energy and eventually heat. Reflection occurs when energy is echoed off the tissue, especially when the wave meets a new tissue interface or medium. Reflected energy is often partially absorbed, dispersed, or scattered. Finally, refraction of a wave refers to a change in speed, wavelength, and direction due to the wave transmitting through a new medium interface. Refraction is also said to effect US wave attenuation.<sup>18</sup> Thus, US waves can be refracted or reflected before being absorbed into the tissue.

When transmitted through musculoskeletal tissue, US waves can affect intrinsic tissue properties and produce thermal and mechanical effects. The primary advantage of therapeutic US

over non-acoustic thermal modalities is the different levels of absorption efficiency through body tissues.<sup>3,6,18</sup> Additionally, US waves have a greater capability of penetrating deeper into tissue than other thermal modalities, thus allowing for deeper tissue heating.<sup>3</sup> The Law of Grotthus-Draper states: 1.) US penetrates through tissues of greater water content, 2.) US waves are absorbed in tissues high in protein, 3.) US waves reflect off bone, and 4.) US waves refract through joints.<sup>3</sup> Due to these properties of US waves, clinicians are able to selectively heat collagen-rich tissues such as tendons, muscles, ligaments, joint menisci and capsules, cortical bone, nerve roots, and periosteum while readily penetrating through skin and adipose, which are rich in water content.<sup>3,18</sup> The effectiveness of thermal US treatments will depend on how well the target tissue will absorb US waves. Given these unique properties of US waves, combined with the simplicity of application and often shorter treatment durations, data has indicated US is a commonly applied modality by clinicians for common musculoskeletal conditions.<sup>7,11,13</sup>

## **2.2. Biomechanics of Therapeutic Ultrasound**

### **2.2.1. Mechanical Effects of Ultrasound**

The biophysical effects of therapeutic US on tissue are mechanical and thermal.<sup>6</sup> Mechanical effects of US are generally associated with physical events occurring within the target tissue, while thermal effects of US are associated with heating due to increase in metabolic activity and blood flow.<sup>10</sup> Avoidance of thermal effects is accomplished in US treatments by altering parameters of the duty cycle from a continuous (e.g. 100%) output to a pulsed (e.g. 25%) output, as well as the intensity of the US wave being delivered.<sup>24</sup> Researchers propose it is best to assume mechanical effects will occur during thermal and non-thermal treatments. Quality research existing on clinical impacts of the mechanical effects of US treatment is lacking. Analysis by Baker and Falconer et al<sup>9,10</sup> has suggested research of the proposed biophysical

mechanical effects of US to be inconclusive. Despite the potential lack of separate thresholds between the mechanical and thermal effects of US, it is convenient to classify effects of therapeutic US as thermal or mechanical (non-thermal). Desired mechanical effects from the use of US stem from the following mechanisms: acoustic streaming, cavitation, and microstreaming.<sup>17</sup>

To understand the proposed clinical effects of mechanical US, biophysical mechanisms of mechanical US must be examined. The first important component of mechanical US is cavitation. While cavitation refers to a general bubble formation phenomenon, it will be used here to refer specifically to acoustic cavitation in the presence of US. This is defined as: “the formation of tiny gas bubbles in the tissues as a result of US vibration”.<sup>10p(1353)</sup> These bubbles are submicron-sized and are classified as either steady vibrations (stable cavitation) or rapidly collapse (unstable cavitation).<sup>15</sup> Stable cavitation occurs when bubbles vibrate steadily, which is hypothesized to produce beneficial bio-effects such as heat generation, increased cellular membrane perforation, and changes to vascular micropermeability.<sup>15,18,39</sup> In addition to cavitation, acoustic streaming is also present during US application. Acoustic streaming is defined as the process in which US waves move the fluid (or gas) through which it propagates away from the transducer head.<sup>14</sup> En vivo acoustic streaming from US treatment can induce or halt blood flow and temperature change in tissue. These two independent processes, cavitation and acoustic streaming, are central in US’s effects on acutely injured tissue.

Researchers of US mechanical effects are particularly interested in tissue changes occurring at a cellular level. The interaction of cavitation and acoustic streaming produces acoustic microstreaming around the cells.<sup>18</sup> Microstreaming is defined as the unidirectional movement of fluid along the boundaries of cellular membranes.<sup>18</sup> Microstreaming is the key

factor in producing cellular changes, both intracellularly and at the cell membrane.<sup>18,21</sup> Changes are suggested to include: altered cell membrane permeability,<sup>15</sup> change in fibroblast function,<sup>17,21</sup> and stimulation of protein synthesis.<sup>17,21</sup> Haar et al<sup>6</sup> concluded modifications to cellular tissue can lead to altered concentration gradients across membranes, which in turn affect ion diffusion and ion concentration following US exposure. Some researchers<sup>6,17,18</sup> propose the biophysical occurrences listed above can lead to important clinical applications of mechanical US including soft repair tissue, enhancement of collagen synthesis, and scar tissue repair. However, other researchers<sup>10,17,18</sup> have concluded these changes have little clinical significance due to the mechanical effects being observed in vitro (animal) studies.

Despite the absence of thermal changes during US application, mechanical effects produced in the tissue from US treatment are regarded as having a potential impact in a clinical setting. While it is important to recognize mechanical effects of US treatments can be beneficial in the treatment of acute soft tissue injury, they are not the focus of this study. The thermal effects of US will be the focus of this review from this point onward.

### **2.2.2. Thermal Effects of Ultrasound**

Thermal effects of US refer to the changes in tissue properties resulting from heating caused by US waves. As US waves transmit through the tissues, the waves are gradually absorbed. Acoustic absorption of the oscillating sound waves by the tissue results in temperature increases within the tissue.<sup>6</sup> Thermal US has been traditionally used for the absorption of pitted edema,<sup>12</sup> reducing muscle spasm,<sup>3,18</sup> reducing pain,<sup>18,24</sup> increasing scar tissue extensibility,<sup>9,18</sup> and reducing joint stiffness.<sup>3</sup> Thermal US is often referred to as continuous US because the duty cycle of the treatment is 100%. In other words, the US unit and transducer will continuously generate US waves which will penetrate into the tissues for the entire duration of the treatment.<sup>18</sup>

It is important to remember the mechanical effects of US will also be present within the tissue in conjunction with the thermal effects.<sup>6,10,14</sup> When applied properly, thermal US can have acute and lasting effects on musculoskeletal tissues. Clinicians must acknowledge patient benefits of the application of US treatment and administer the modality when indicated for reaching treatment goals.

Clinicians who provide US treatments must also be sure to consider patient safety. There is an established set of contraindications for use of therapeutic thermal US clinicians need to consider when treating human patients. Some contraindications for thermal US include application to acute inflammation, ischemic areas, and areas with impaired circulation. Compromised blood flow can prevent the body from dissipating excessive heat generated from the US waves which result in burning of the treatment area.<sup>16</sup> Additionally, areas of active deep vein thrombosis (DVT) or thrombophlebitis are contraindicated for US use, as applications over areas of a possibly active DVT can dislodge the clot into the circulatory system.<sup>16</sup> Ultrasound should never be used in the treatment of potentially cancerous lesions as US has the potential to spread active cancerous lesions.<sup>16</sup> Similarly to cancerous lesions, US applied over infected areas can potentially spread the infection, thus it should be avoided. In addition, if used over an active fracture site, including stress fractures, US may cause delayed healing if applied thermally.<sup>16</sup> Lastly, US should not be applied over metal implants in the skin, and should not be administered to pregnant women.<sup>16,18</sup> It is crucial that clinicians are aware of contraindications of thermal US and not simply administer the treatment absentmindedly.

Certain therapeutic thermal effects of US can only be achieved by reaching specific tissue temperature thresholds. Weaver et al<sup>25</sup> concluded tissue temperatures must be raised to a level of 104-113°F (40-45°C) for a minimum of five minutes for most thermal effects to occur. Tissue

temperatures above 113°F (45°C) can be dangerous and cause damage.<sup>18</sup> Other researchers have suggested increasing tissue temperature to a specific threshold should not be the focus of US treatment. Rather, the amount of increase from the patients' baseline temperature is the key to achieving desired effects from the US application.<sup>5,6</sup> The consensus among these researchers<sup>9,23</sup> and modality textbooks<sup>16,18</sup> suggests the following heating thresholds for therapeutic intervention: a tissue temperature increase of 1°C (1.8°F) over baseline temperature increases metabolism and healing, an increase of 2-3°C (3.6°F-5.4°F) can decrease pain and muscle spasm, and an increase of 4°C (7.2°F) or greater can increase collagen extensibility and decrease joint stiffness. When using therapeutic thermal US, clinicians need to understand the purpose and goals of the treatment. Ensuring the corresponding tissue heating threshold is reached within the treatment duration is vital to the effectiveness of the modality.

Stretching of connective and muscular tissue is one of the primary indications for a thermal US treatment.<sup>3,6,24,18</sup> Connective tissue is more rigid when stretched, however, the tissue can be slightly lengthened after it has been heated.<sup>25</sup> After heat has been applied to connective tissue, joint and tissue mobilization techniques can be performed to manipulate the tissues' elasticity. In the same manner, a manual stretch to muscular tissue from a clinician after heating will result in the residual lengthening of the tissue.<sup>18</sup> The clinician can manipulate the amount of stretch by applying different levels of force to the muscle. If the clinician's treatment goals include tissue elongation, it would be optimal to implement forms of stretching or tissue mobility work after the application of US.

As the potential for tissue extensibility and elongation after heat application is finite, the time period directly after US treatment is referred to as the stretching window.<sup>12,18</sup> It has been hypothesized the stretching window only lasts around five to ten minutes after the end of a

thermal US treatment;<sup>18</sup> however, this window may be much shorter. Draper and Ricard<sup>27</sup> examined the duration of elevated tissue temperatures from US. They administered 3 MHz, 1.5 W/cm<sup>2</sup>, 6-minute, thermal US treatments to 20 healthy individuals. The treatments resulted in the triceps surae tissue temperature increasing at least 5°C above baseline temperatures. Tissue temperatures cooled to a level below 4°C in an average of 3.3 minutes after US termination, losing potential for collagen alteration. If tissue temperature was only raised 4°C, it would subsequently take less than two minutes to lose potential for alteration.<sup>27</sup> Researchers observed clinicians often neglect the utilization of the stretching window and potentially are oblivious to its existence or importance.<sup>12</sup> For clinicians who use US for intramuscular heating, the stretching window provides an opportunity to help elongate soft tissue when indicated for patient soft tissue injury.

## **2.3. Prevalence**

### **2.3.1. US Treatment Prevalence**

Therapeutic US is used by physical therapists and ATs in the United States for the treatment of common musculoskeletal pathologies. Instructors for modality courses, as well as textbook authors, teach athletic training students about therapeutic US. However, no research currently exists on the prevalence of its clinical use by ATs. For physical therapists, several surveys have been conducted to determine the frequency of clinical US use. In 2007, researchers surveyed the use of therapeutic US in the United States among physical therapists who were also orthopedic certified specialists. The survey was made available to 457 practicing physical therapists and 213 responses were obtained.<sup>11</sup> The responses indicated 83.6% of physical therapists believed therapeutic US was best indicated for use in the treatment involving soft tissue inflammation (i.e., tendonitis/bursitis).<sup>11</sup> Following soft tissue inflammation, tissue

extensibility (70.9%), scar tissue remodeling (68.8%), and tissue healing (52.5%) were the next three most indicated conditions for use of therapeutic US.<sup>11</sup> A total of 79% of respondents used therapeutic US at least once per week and 45% used US more than 10 times per week. Based on responses from the survey, it was suggested therapeutic US is a commonly applied modality by physical therapists in the United States as a therapeutic intervention for the treatment of musculoskeletal tissue pathologies. While ATs are instructed on US and its clinical application, the frequency of use of US by ATs in the United States has not been researched.

Additionally, therapeutic US is used as a modality in the United Kingdom (UK), as well as Australia. In a 2007 questionnaire exploring the availability and use of therapeutic modalities in physiotherapy clinics in the UK, therapeutic US devices were found to be available in all responding physiotherapy departments (n=46).<sup>7</sup> None of the surveyed departments reported avoiding the use of US as a treatment option, suggesting US is used throughout the UK.<sup>7</sup> Researchers in Australia also examined physiotherapists' application of US as a therapeutic modality. A survey questionnaire was sent to 380 physiotherapists about their use and perception of efficacy related to therapeutic US, of which 210 responded. It was reported continuous US was the most frequently used modality among respondents, with 48% of physiotherapists ranking US as their first choice.<sup>13</sup> Respondents selected "tissue healing" and "thermal properties" as the two main factors influencing their choice to use US.<sup>13</sup> In regards to respondents' reasoning for the use of US as a treatment, the placebo effect (61.3%) received the highest response rate, followed by treatments of chronic scar tissue (57.2%), acute bursitis (54.2%), acute tendonitis (54.2%), and chronic muscle strain (54.2%).<sup>13</sup> Researchers used data obtained in this survey to calculate daily usage of US to be 70% for surveyed physiotherapists.<sup>13</sup> Overall, researchers have



used surveys to indicate therapeutic US is one of the most frequently used modalities by physical therapists and physiotherapists across the world in treatment of musculoskeletal pathologies.

## **2.4. Ultrasound Treatment Parameters**

Ultrasound treatment parameters refer to the variables which can affect either properties of the electric current produced by the generator or the US waves emitted from the transducer, four of which are directly chosen by the operator. The operator of the US unit will have direct control over the frequency, intensity, duty cycle, and duration of the treatment. Draper<sup>12</sup> states four of the most commonly made mistakes of therapeutic US application are directly related to incorrect treatment parameters chosen by the clinician. It is of vital importance treatment parameters are properly set by the clinician to ensure useful therapeutic outcomes as well as protecting the patient from further injury.<sup>12</sup> Other parameters such as the beam non-uniformity ratio (BNR) and the effective radiating area (ERA) are not controlled by the operator, but rather determined by the manufacturer. Having a fundamental knowledge of US parameters can assist a clinician in conducting an appropriate treatment for a patient's condition.

### **2.4.1. Ultrasound Mode or Duty Cycle**

The mode of US, sometimes referred to as duty cycle, is a parameter set by the clinician that will alter the amount of time the transducer actively emits US waves. This affects the total amount of sound energy delivered to the patient over the course of the treatment. The mode is commonly referred to as either being continuous or pulsed. When performing continuous US, the transfer of ultrasonic energy from the unit to the patient remains constant throughout the treatment. On the other hand, pulsed US will intermittently stop the transfer of ultrasonic energy to the patient at set intervals, delivering energy in more of a pulsing fashion.<sup>18</sup> Pulsed US reduces the temporal average intensity (TAI) of the treatment, which is the amount of energy delivered

over a treatment time.<sup>16,18</sup> The percentage of time US is actively generated (pulse duration) over the total time US has the potential to be generated (pulse period), is referred to as the duty cycle.<sup>18</sup>

$$\text{Duty Cycle}^2 = \frac{\text{Pulse length}}{(\text{Pulse length} + \text{Pulse interval}) \times 100}$$

For example, if a pulse duration is 30ms, and the pulse period is 60ms, the duty cycle would be 50%. The closer the duty cycle is to 100%, the greater the thermal effect of the US treatment. Most US units come with preset controls to manipulate the duty cycle.<sup>18</sup> Selecting the correct mode/duty cycle depends on the established treatment goals for the patient, and how much ultrasonic energy is needed in reaching said goal.

#### **2.4.2. Ultrasound Frequency**

Similar to altering the thermal potential of an US treatment using mode, clinicians are also able to manipulate the depth of US wave penetration using frequency. Ultrasound waves are emitted from the transducer in the form of a collimated beam with varying divergence.<sup>18</sup> As an US wave transmits through body tissues, a more concentrated wave will be absorbed more readily than a diverged wave.<sup>18</sup> As the frequency of a wave increases, the less the wave will diverge, and a more focused wave will be produced. Therefore, penetration and absorption of ultrasonic energy are based on the frequency of the US waves.<sup>18</sup> As the frequency of US waves increases, the more readily the wave is absorbed, and vice versa. This makes frequency an incredibly important parameter for effective US treatments to reach the target tissue.

As the penetration depth of US waves increases with a lower frequency, the chance for waves to reflect or refract increases. Wave reflection refers to waves bouncing off tissue, while refraction refers to waves slightly changing direction as they pass through a new medium. Reflection and refraction of waves often occur when US reaches a barrier such as fascia or bone

and can potentially hinder therapeutic effects of treatment.<sup>16</sup> Selecting the appropriate frequency according to the depth of the target tissue will help minimize reflection and refraction of waves and maximize energy absorption.

Most available US units have options for frequency input between 1.0 MHz and 3.0 MHz. Several textbooks<sup>16,18,33</sup> recommend lower frequency US treatments can heat tissue up to 5 cm deep, while higher frequency treatments are recommended for use on tissue up to 2-3 cm deep. Draper et al<sup>5</sup> were the first researchers to examine in vivo use of 3 MHz US frequency, comparing it to 1 MHz treatments. Twenty-four healthy college students were randomly divided into two groups to receive US treatments in the left triceps surae muscle group. Twelve participants received 3 MHz US treatments at depths of 0.8 cm and 1.6 cm, and the other twelve received 1 MHz treatments at depths of 2.5 cm and 5 cm. These depths were selected based off hypothesized half-value layers of US. Half-value is the depth by which 50% of the US beam is absorbed in the tissue.<sup>6</sup> Four treatments with intensities of 0.5, 1.0, 1.5 and 2.0 W/cm<sup>2</sup> were administered to each subject in a random order, allowing the tissue to return to baseline temperature between each treatment. The treatment duration lasted either 10 minutes or until the subject became uncomfortable due to heating. To ensure consistent application areas between participants, a template was applied to patients before treatment. Additionally, transducer velocity was recorded consistently to be 2-3cm/s for all participants. All US treatments were performed on an Omnisound 3000™ and tissue temperature was recorded every 30 seconds.

The results indicated a 3 MHz treatment heated tissue at least three times faster than 1 MHz. Superficially, the 3 MHz heating effect was four times greater than the 1 MHz. At the deep tissue sites, the effect of 3 MHz was three times greater than the 1 MHz treatments at all doses ( $P < .001$ ). In addition, no significant differences existed in the final tissue temperature between the

two 3 MHz depths ( $P = .084$ ), as well as the 1 MHz depths ( $P = .987$ ) at all treatment doses.<sup>5</sup>

Draper et al concluded 3 MHz US treatments heated faster and greater than 1 MHz treatments of the same intensity. However, they stressed future studies space apart US treatments in subjects by at least one day, believing this would produce more predictable and reproducible data.

Building off the research by Draper et al<sup>5</sup>, Hayes et al<sup>26</sup> further examined the use of 1 MHz and 3 MHz treatments. In their experiment, 18 healthy volunteers were randomly divided into either 1 MHz or 3 MHz frequency treatment groups. Ultrasound was then applied continuously for 10 minutes at  $1.5 \text{ W/cm}^2$  to the medial triceps surae muscle using a Theratouch 7.7 US device and intramuscular temperature was recorded at a depth of 2.5 cm. After the treatment, the time taken to produce vigorous heating in the muscle ( $4^\circ\text{C}$ ) was compared. Hayes et al reported the 1 MHz treatments did not produce therapeutic vigorous heating in the 10 minute treatment ( $4^\circ\text{C}$ ), while the 3 MHz treatment produced therapeutic vigorous heating 4.13 ( $\pm 1.69$ ) minutes into the treatments.<sup>26</sup> The heating rates of the 1 MHz treatments were found to be  $0.13^\circ\text{C/min}$ , while the 3 MHz treatments heated at a rate of  $1.19^\circ\text{C/min}$ . In comparison, Draper et al<sup>6</sup> reported heating rates of  $0.3^\circ\text{C/min}$  for 1 MHz and  $0.9^\circ\text{C/min}$  for 3 MHz treatments at a corresponding  $1.5 \text{ W/cm}^2$  intensity. Comparing the results of these studies, the Omnisound 3 MHz treatments heated only three to four times faster than 1 MHz; while the Theratouch 7.7<sup>26</sup> at 3 MHz heated ten times faster than the 1 MHz treatments. The difference in these findings potentially highlights discrepancies in heating capabilities between US units.

Based on the findings, the researchers<sup>26</sup> suggested therapeutic modality textbook recommendations underestimate the depth of penetration of 3 MHz US treatments. Additionally, they suggested further research should be conducted to explore various US machines and their frequencies in terms of absolute temperature increases and rates of temperature increase.<sup>26</sup>

Selecting the appropriate frequency for US treatment is essential for heating target tissues to a level of therapeutic significance, and additional research is needed to clarify the extent of US depth of penetration and effectiveness of heating in regard to frequency selection.

### **2.4.3. Ultrasound Intensity**

Selecting US intensity is another important factor in reaching target thermal thresholds during US application. The intensity of an US treatment refers to the rate at which energy is being delivered per unit area, usually expressed in watts per square centimeter ( $\text{W}/\text{cm}^2$ ).<sup>18</sup> Spatial average intensity (SAI) refers to the intensity of the US beam averaged over the area of the active transducer.<sup>18</sup> The SAI is calculated by taking the total power produced by the treatment (Watts) divided by the total effective radiating area (ERA) of the transducer ( $\text{cm}^2$ ). Thus, if an US treatment produced a power of 4W and the ERA of the soundhead is 4  $\text{cm}^2$ , the SAI would be 1.0  $\text{W}/\text{cm}^2$ . According to the World Health Organization's guidelines,<sup>18</sup> a SAI of 3.0  $\text{W}/\text{cm}^2$  is the safe limit for treatment with therapeutic US. Increasing the intensity above 3.0  $\text{W}/\text{cm}^2$  can potentially cause tissue damage,<sup>9</sup> and intensities above 10  $\text{W}/\text{cm}^2$  can destroy tissue.<sup>18</sup> While there are limits on maximal SAI, no current definitive guidelines exist for intensity selection for US treatments. Clinicians are taught to alter US intensity in conjunction with treatment time to reach an appropriate increase in tissue temperature capable of meeting therapeutic goals.

In addition to the 1 and 3 MHz frequencies Draper et al<sup>6</sup> examined in their 1995 study, several intensity doses of each frequency were also explored. With an Omnisound 3000™ US unit, a significant difference ( $P < .001$ ) was recorded amongst all four intensities (0.5, 1.0, 1.5, 2.0  $\text{W}/\text{cm}^2$ ) in both treatment categories. The observed heating rates given intensity dosage and frequency selection are found in Table 1.

**Table 1***Draper et al<sup>5</sup> Observed Heating Rates with Omnisound 3000<sup>TM</sup> Ultrasound Unit*

Intensity (W/cm <sup>2</sup> )	1 MHz (°C/min)	3 MHz (°C/min)
0.5	0.04	0.3
1.0	0.2	0.6
1.5	0.3	0.9
2.0	0.4	1.4

However, it is imperative to mention researchers found no interaction between intensity and depth ( $P = .39$ ), and intensity had no effect on how deep US penetrated. In addition, Draper et al<sup>9</sup> reported inconsistent heating percentage increases based on the researchers hypothesized values of 1 MHz US application. The 1.5 W/cm<sup>2</sup> heated 100% faster than the 1.0 W/cm<sup>2</sup> treatment, and the 2.0 W/cm<sup>2</sup> heated 230% faster than the 1.0 W/cm<sup>2</sup> treatment. In the 3 MHz applications, the 1.0 W/cm<sup>2</sup> heated 51% faster than the 0.5 W/cm<sup>2</sup> treatment, this was consistent between the 1.0 W/cm<sup>2</sup> and 1.5 W/cm<sup>2</sup> treatment as well. These results demonstrated inconsistent rates between 1 MHz doses, but consistent rates between 3 MHz doses. The results of this study have helped define clinical knowledge regarding intensity and are still used by clinicians for setting thermal US parameters. Furthermore, these results are cited in therapeutic modality textbooks<sup>5,16,18</sup> still used today. Additional research is needed to further explore differences between common intensities selected by clinicians, as well as how thermal effects may differ between two US units from the same manufacturer with the same treatment intensity.

#### **2.4.4. Ultrasound Treatment Duration**

Ultrasound treatment duration is another crucial parameter clinicians must consider to appropriately treat pathology. The length of the treatment is formulated around several factors including: the size of the treatment area, frequency, intensity, and the desired increase in tissue temperature.<sup>12</sup> In regard to intensity, any significant adjustment in treatment intensity should be

countered with an appropriate adjustment to treatment time. If the intensity of a treatment is increased, ultrasonic energy is being transferred at an increased rate. Therefore, treatment duration should be decreased to prevent overheating and damage to the target tissue. Like intensity, higher frequency US treatments require shorter treatment times. It is suggested 3 MHz treatments consistently heat tissue three times faster than 1 MHz treatments.<sup>6</sup> Therefore, researchers recommend reducing treatment times by one third when applying US at a 3 MHz frequency.<sup>12,18,27</sup> Based on these factors, the duration of US treatments are a function of both intensity and frequency. With the application of US, clinicians must determine their treatment goals, select the appropriate frequency and intensity for their treatment, and finally choose an appropriate treatment duration based on their selected parameters. For example, to achieve vigorous heating (4°C) with a 3 MHz, 1.5 W/cm<sup>2</sup> US treatment using the results of Draper et al<sup>6</sup> (Table 1), the clinician must apply thermal US for about 4.5 minutes [ $4^{\circ}\text{C}$  (treatment goal) / 0.9°C per minute (heating rate)] to reach the desired temperature increase. Knowing how parameters influence US treatments will ensure appropriate thermal thresholds are reached and the patient is not harmed during the treatment.

Treatment duration not only refers to individual treatment times, but also the total number of US treatments given to a patient. A lack of research exists on the total number of US treatments a clinician should perform to maximize treatment goals. Knight and Draper<sup>18</sup> recommend limiting US to a maximum of 14 treatments in their modality textbook. They state after 14 US treatments; red and white blood cell counts may decrease. However, no research has been published confirming the reduction of RBC or WBC counts. Therefore, it is unknown as to the effectiveness of a set number of treatment sessions.<sup>18</sup> Furthermore, alternative parameters or modalities should be considered if no improvement is noted over four or five treatments.<sup>18</sup>

According to Starkey's<sup>16</sup> modality textbook, US is normally given once per day for 10 to 14 days after which the efficacy of the treatment protocol should be evaluated. Additionally, the Prentice<sup>33</sup> modality textbook recommends treatment with US once or twice daily for 6 to 8 days for acute conditions, and to continue US treatment for insidious conditions until no more improvement is noted. Additional research is needed to discern the appropriate regularity of US treatments, as well as the optimal number of total US treatments for a patient.

#### **2.4.5. Ultrasound Effective Radiating Area**

Effective radiating area (ERA) is another important property of US application to consider when examining heating capabilities of various units. The ERA refers to the surface area on the US transducer which transmits US waves from the crystal to tissue.<sup>18</sup> Measuring the pulse intensity integral over a planar surface 5 mm from the face of the transducer will net the ERA value for that transducer. A transducer's pulse intensity integral is the time integral of instantaneous intensity at a point over the time where acoustic energy is being produced. While measuring the integral, all areas of the transducer which produce more than 5% of the maximum power output on the surface of the transducer are recorded.<sup>18,29</sup> Since the crystal within the transducer is always smaller than the transducer face itself, the ERA will always be smaller than the surface area of the transducer plate.<sup>18</sup> Any manufacturer claiming ERA of an US transducer is the same area as the size of the transducer face has not appropriately scanned the crystal for quality.<sup>12</sup> It is beneficial to use US transducers and crystals which approximately match the ERA in terms of surface area or size to maintain maximal effective contact with the treatment area.

In terms of selecting the US treatment area, knowing the given manufacturer ERA is important. Researchers have investigated possible US treatment areas in terms of the crystal ERA. Garret et al<sup>28</sup> conducted a clinical trial comparing the increase in intramuscular tissue



temperature after treatments of short-wave diathermy or US. The US treatment applied to participants' calf muscle was set at a frequency of 1 MHz and an intensity of 1.5 W/cm<sup>2</sup> for 20 minutes. Thermocouples were inserted in participants' calf musculature at three locations, 5 cm apart and 3 cm deep, and intramuscular tissue temperatures were collected every minute using an Iso Thermex. The US treatment area was approximately 40x the ERA of the unit (Omnisound 3000). This was set as the treatment area to compare to the diathermy treatment area. No significant changes in tissue temperature means were observed between pre and post US treatments at any of the sites (site 1:  $\Delta^{\circ}\text{C} = 0.20 \pm 0.38$ , site 2:  $\Delta^{\circ}\text{C} = 0.09 \pm 0.54$ , site 3  $\Delta^{\circ}\text{C} = -0.44 \pm 0.44$ ).<sup>28</sup> Based on the results, Garret et al suggested US will not produce clinically significant temperature increases over large treatment areas with respect to the ERA.

In addition to research comparing 40x the ERA, Chan et al<sup>38</sup> compared treatment areas of two times and four times the manufacturer reported ERA and the corresponding temperature increases within 16 subjects' healthy patellar tendons. The Omnisound 3000<sup>TM</sup> US unit with a 5 cm<sup>2</sup> transducer and 4.5 cm<sup>2</sup> manufacturer reported ERA was utilized with the following parameters: 3 MHz frequency and 1.0W/cm<sup>2</sup> intensity for four minutes. The treatment area was contained using templates either two or four times the manufacturer reported ERA. Researchers reported treatments two times the ERA resulted in higher tissue temperatures ( $8.3^{\circ}\text{C} \pm 1.7$ ) compared to treatments four times the ERA ( $5.0^{\circ}\text{C} \pm 1.0$ ). Both treatments resulted in temperature increases of at least 4°C, which is considered the vigorous heating threshold. Based on these findings, the researchers<sup>38</sup> concluded a treatment area two times the reported ERA was more effective at heating patellar tendon tissue compared to an area four times the reported ERA.

Continuing in the examination of effective ERA and treatment areas, Knight and Draper<sup>18</sup> referenced studies by Demchak et al<sup>18p(264)</sup> and Chudleigh et al<sup>41</sup> in their modality textbook.

These studies examined tissue heating by US treatment over areas four and six times the size of the soundhead, respectively. The study by Demchak et al could not be located; therefore, the methodology is unknown and the ability to compare results with similar studies, such as Chan et al<sup>38</sup> is impossible. However, the results of the study are reported in the Knight and Draper text as follows: “Demchak et al reported a mean capacity temperature increase of 2°C for an area four times the soundhead. Based on the results, researchers suggest only moderate heating can be achieved for treatment areas of these sizes.”<sup>18p(264)</sup> For the research conducted by Chudleigh et al,<sup>41</sup> only an abstract could be located. In the study, researchers compared temperature rise in the posterior calve of 20 subjects when using US treatment areas 2 and 6 times the ERA. Before treatment, subjects were randomly divided into either a 1.5 W/cm<sup>2</sup> or a 2.0 W/cm<sup>2</sup> US intensity group. This was done to examine if an increased intensity may impact temperature discrepancies created by the larger treatment area. All US treatments were applied at a frequency of 1 MHz and were 10 minutes in duration; and tissue temperature was measured via intramuscular thermocouples at a depth of 4 cm below the skin. Upon comparison, significant differences were found for treatment area, with the 2x ERA treatments heating significantly more (mean 3.5°C) than the 6x ERA treatments (1.3°C, p = .0001). There were no significant differences between the two intensities, as well as no interaction effect of the two variables. The researchers concluded with the recommendation of using a treatment area of 2 times the ERA for effective tissue heating and stressed to not increase treatment intensity in attempt to compensate for an increased treatment area.<sup>41</sup>

Given the currently literature, modern modality textbooks<sup>5,16,18</sup> recommend treating an area two to three times the ERA to effectively heat tissue to vigorous levels. Clinicians often adhere to these recommendations. However, US may be effective at producing moderate heat in

areas four to six times the ERA depending on the type of tissue heated.<sup>18</sup> Clinicians should dictate treatment goals and ensure the targeted area for US application is appropriate for achieving the heating thresholds required for effective treatment.

Knowing the ERA of an US transducer is important in determining the treatment area. Researchers have shown ERA of US transducers may vary between manufacturers. Johns et al<sup>30</sup> examined 66 5 cm<sup>2</sup> new US transducers purchased from six different manufacturers (Chattanooga, Dynatron, Mettler, Omnisound, Rich-Mar, and XLTEK). The ERA of the 66 transducers (n=11 each group) was measured using an underwater microphone at a testing frequency of 3 MHz. Before testing, every transducer was independently calibrated to within  $\pm$  15% according to manufacturer's guidelines. A laboratory power amplifier was used to generate the electrical drive to the soundhead instead of using each manufacturer's unit. In terms of intensity, each manufacturer transducer SAI was set to the value obtained by dividing power of 5W by the manufacturer reported ERA. For example, the reported ERA of a Dynatronics transducer was 5 cm<sup>2</sup>, therefore making the SAI at 5 W 1.0 W/cm<sup>2</sup>. These values were then normalized for direct comparison. This was performed to ensure accurate measurements, decreased interference, and consistent parameters of the measurement process.

After calibration, the pulse intensity integral was measured over a planar surface 5 millimeters from the face of the transducer and calculated as the area over which the intensity was greater than 5% of the peak intensity. After data analysis, the measured ERA values were compared to the manufacturer reported ERA values for the transducers. It was reported only three transducers (Chattanooga n=2, Mettler n=1) showed ERA values outside of the reported tolerance of their respective manufacturer cohort ( $\pm$ 1.0 cm<sup>2</sup>). However, five of the six

manufacturers had ERAs different ( $P < .001$ ) from the values they reported, except Omnisound<sup>30</sup> (Table 2).

**Table 2**

*Johns et al<sup>30</sup> Reported vs Measured Transducer ERA*

Transducer Manufacturer	Reported ERA (in cm <sup>2</sup> )	Measured ERA (in cm <sup>2</sup> )
Chattanooga	4.0 ± 1.0	4.89 ± 0.29
Dynatron	5.0 ± 1.0	4.83 ± 0.11
Mettler	5.0 ± 1.0	5.64 ± .30
Omnisound	4.5 ± 0.4	4.56 ± 0.6
Rich-Mar	5.0 ± 1.0	4.55 ± 0.33
XLTEK	5.0 ± .75	5.56 ± 0.15

Incorrect manufacturer reported ERA values can adversely affect the effectiveness of US treatment over a selected area. Consequently, clinicians must be aware of potential discrepancies in reported ERA values.

#### **2.4.6. Ultrasound Beam Non-Uniformity Ratio**

Ultrasound waves do not attenuate through a medium in a completely uniform fashion, and individual wave intensities can vary throughout the treatment. The beam non-uniformity ratio (BNR) quantifies the variability of intensity within the US beam. Specifically, the BNR of an US unit is measured as the spatial peak intensity (the most intense point of the US wave) compared to the spatial average intensity (the average intensity across the whole beam).<sup>30</sup> When an US beam is set to 1 W/cm<sup>2</sup> and the highest intensity of the beam can reach up to 4 W/cm<sup>2</sup>, the BNR of the US unit is measured as a 4:1 ratio. The BNR of US units is commonly measured via an underwater hydrophone to record intensity.<sup>18,30</sup> Like other US parameters, it is important clinicians who administer US understand what BNR is and how it is measured to ensure proper use of the modality.

$$\text{BNR}^2 = \frac{\text{Spatial peak intensity}}{\text{Spatial average intensity}}$$

Knowing the BNR of the US unit is important for patient safety. The optimal BNR for any US unit would be a 1:1 ratio, which provides the most uniform beam possible. It is impossible to produce an US unit with an exact 1:1 BNR, but it should be the goal to get BNR as close to 1:1 as possible. Large variability in beam uniformity can make US ineffective or dangerous for treating musculoskeletal conditions. Ultrasound units with higher BNRs can cause tissues under the transducer to receive more energy than intended, which can lead to discomfort or pain.<sup>18</sup> Knowing the BNR of US units can prevent patient discomfort and allow clinicians to know when it is safe to administer higher intensity treatments without potentially harming the patient.

Beam non-uniformity ratios of US machines vary significantly. Ferrari et al<sup>30</sup> studied 31 US units used at least five times daily by physiotherapists in Brazil. While the average value of BNR reported by the therapists was 2.8:1, the measured range of BNR was 1.61:1 to 9.49:1.<sup>30</sup> The United States Food and Drug Administration (FDA) Center for Devices and Radiological Health has required US unit manufacturers to report BNR. All US unit manufacturers must report the maximum BNR for the unit brand.<sup>18</sup> The FDA dictates BNRs of <8:1 are acceptable for use in the United States. Knight and Draper<sup>18</sup> recommend a BNR between 2:1 and 5:1 for clinical US use. However, the maximum BNR reported for an US unit is only required to be formed based on a random sample of units and may not accurately represent the BNR for each specific unit.<sup>18</sup> Due to the potential variance of BNR between brands, it is essential for clinicians to be aware of BNR values before purchasing units. Additionally, it is important for machines to receive appropriate maintenance and calibrations to ensure patient safety.

## 2.5. Clinical Effectiveness of Ultrasound

Therapeutic US application is thought to provide beneficial effects for function and pain reduction in regards to musculoskeletal pain and injury.<sup>8,9,19</sup> However, researchers have found inconclusive evidence for the use of US in a clinical setting.<sup>1,4,9,10,20</sup> Windt et al<sup>4</sup> examined five clinical trials where US treatments were used for rehabilitation of acute ankle sprains. All the trials included two groups, one group receiving an US treatment and the other receiving a sham US treatment. The researchers reported improvements in the US group for decreasing swelling (25% increase) and pain reduction (20%) in one trial, but the criteria for clinical significance were not specified. The other trials showed no statistically significant differences between groups for pain, swelling, range of motion, or functional disability.<sup>4</sup> Thus, researchers suggested US did not merit clinical use based on the lack of significant differences between US and a sham placebo.

Likewise, Falconer et al<sup>9</sup> compared 31 clinical trials where US therapy was used in the treatment of various chronic inflammatory conditions. The criteria for inclusion in the review was as follows: the trials included the use of a placebo or sham control group; and US intensity, frequency, mode of delivery (continuous or pulsed), treatment duration, and treatment frequency were provided for the treatment groups. Comparing the outcomes of the 31 selected trials, researchers reported US used for the treatment of pain and contracture in chronic inflammatory conditions was not justified due to the lack of differentiation of effectiveness between US and placebo treatments.<sup>9</sup> In terms of the proposed physiologic effects of US, Baker et al<sup>10</sup> conducted a narrative review of existing research on the biophysical non-thermal and thermal effects of US. Based on research reviewed, Baker et al<sup>10</sup> deducted evidence for the biophysical rationale regarding the use of US is inconclusive, and its effects are unlikely to be beneficial. Given the

existing research mentioned, effectiveness of US remains unsubstantiated in the treatment of musculoskeletal pathology.

Although inconclusive evidence of US effectiveness exists within the current literature, Draper<sup>12</sup> states clinician error in therapeutic US application is common, possibly resulting in ineffective treatments. He suggested inappropriate parameter selection, treatment area, treatment duration, speed of US application, and ignoring acute heating effects post US treatment are all common mistakes made among clinicians using US.<sup>10</sup> Despite this dispute in research conclusions, therapeutic US has been consistently used among clinicians as a treatment option for various pathologies.<sup>7,11,12,13</sup>

## **2.6. Variation among Ultrasound Units by Manufacturer**

The ability of therapeutic US to produce desired thermal effects relies on accurate clinician inputted parameters (frequency, intensity, and treatment time), as well as the ERA and BNR of the unit. The current textbook parameter guidelines<sup>16,18,33</sup> are based off research published by Draper et al<sup>5</sup> using the Omnisound 3000™ US machine. These rates are outlined in Table 1. However, research has begun to emerge suggesting differences exist between US units in terms of tissue heating capabilities.<sup>30,31,32</sup> It is imperative to examine various US machines to ensure clinicians applying US can select appropriate parameters to achieve the correct amount of intramuscular heat required for effective treatment.

### **2.6.1. Ultrasound Prevalence by Unit Brand**

Due to the prevalence of US use as a modality for various conditions, over 10 companies have produced their own brands of therapeutic US machines.<sup>30</sup> Companies that produce therapeutic US units include Accelerated Care Inc. (Topeka, KS), Mettler Electronics (Anaheim, CA), Chattanooga Corp. (Chattanooga, TN), Dynatronics (Salt Lake City, UT), Rich-Mar (Inola,

OK), Power Technologies Inc. (Schenectady, NY), Mid-Canada Medical (Ontario, Canada), Excel (Ontario, Canada), Bosch (Broadview, IL), Amrex (Carson, CA), and Enraf-Nonius (Rontgenweg, Netherlands). Ultrasound unit brand prevalence among clinicians requires further examination from researchers. Artho et al<sup>13</sup> investigated the calibration quality of therapeutic US units used by Texas clinicians, and collected information on the brand and model of each machine examined. Of the 84 machines calibrated, Chattanooga brand machines (n=32) were the most abundant, followed by Enraf-Nonius (n=15), Rich-mar (n=11), and Dynatronics (n=10). The most popular units of the Chattanooga brand machines were the Intellect 700 (n=11), the Intellect Legend Combo (n=5), and the Forte 200 Combo (n=5).<sup>13</sup> Outside of this study, no research has been performed to quantify usage of therapeutic US machines by brand or model. Therefore, emphasis should be placed on future research obtaining information about US unit brand prevalence to establish appropriate treatment protocols for popular brands.

### **2.6.2. Omnisound and Textbook Information**

The Omnisound 3000<sup>TM</sup> heating rates are cited in at least three popular modality textbooks<sup>16,18,33</sup> to guide clinicians in correct parameter selection for the application of thermal US. These heating rates were produced by Draper et al<sup>5</sup> in 1995 and are still often taught to students in therapeutic modality classes today. Despite Omnisound being the most researched US brand, the prevalence of use of Omnisound units is still widely unknown.

Comparing Omnisound units with US units from other manufacturers has become an increasing area of focus for researchers. Holcomb and Joyce<sup>31</sup> compared US administration via an Omnisound 3000<sup>TM</sup> with a Forte 400 Combo (Chattanooga Group Inc.). Both units used in the experiment were new and recently calibrated. The ERAs of each machine were 4.9 cm<sup>2</sup> for the Omnisound and 4.6 cm<sup>2</sup> for the Forte 400 Combo, and the BNRs were 3.7:1 and 2.3:1,



respectively. Ten healthy subjects were randomly assigned to two groups and given continuous US treatments at 3.0 MHz and 1.0 W/cm<sup>2</sup>. Treatments lasted either 10-minutes or until the tissue temperature increased 6°C above baseline. Five subjects received US with the Omnisound unit and five received US with the Forte 400 unit. All subjects received treatment over their healthy left triceps surae muscle. Temperatures were recorded at a depth of 1.2 cm below tissue surface. The experiment demonstrated the Omnisound treatments produced a significantly greater temperature elevation ( $5.81 \pm 0.41^\circ\text{C}$ ) than the Forte 400 combo ( $3.85 \pm 0.75^\circ\text{C}$ ) ( $P < .001$ ). These final temperatures were obtained at a rate temperature increase of 0.58°C/min and a 0.39°C/min for the respected units. The Omnisound 3000 had a 51% greater heating rate at 3 MHz compared to the Chattanooga unit and corroborates the Draper et al<sup>6</sup> established heating rates based on the selected parameters (Table 1). Holcomb and Joyce<sup>31</sup> concluded Omnisound was more effective for heating than the Forte 400. The Omnisound unit had a slightly larger ERA (4.9 cm<sup>2</sup>) and BNR (3.7:1) compared to the Forte 400 (4.6 cm<sup>2</sup> ERA, 2.3:1 BNR); however, even when taking ERA, BNR, and crystal differences into account the researchers could not adequately explain the reason for the discrepancies in effectiveness. This study emphasized the need for further examination into comparing Omnisound heating effectiveness with other US units.

Like the aforementioned study, Merrick et al<sup>32</sup> compared the heating rates of the Omnisound 3000C<sup>TM</sup> with the Excel Ultra III and Dynatron 950. The manufacturer reported and researcher measured ERA values of the unit transducers were: Omnisound: 6.7 cm<sup>2</sup> reported, 9.6 cm<sup>2</sup> measured; Excel Ultra III: 5.0 cm<sup>2</sup> reported, 8.0 cm<sup>2</sup> measured; Dynatron: 5.0 cm<sup>2</sup> reported, 12.6 cm<sup>2</sup> measured. The reported BNRs of each unit were 3.9:1, <4:1, and <6:1 for the Omnisound, Excel Ultra III, and Dyantron units, respectively. Ultrasound treatments (3 MHz, 1.5

W/cm<sup>2</sup>, continuous mode, 10-minute duration) with each unit were administered to six healthy subjects on the left posterior calf of every subject. The treatment area was twice the width of the soundhead, marked by a template, and treatments with different units were performed 24-48 hours apart. Assisted by a metronome, the transducer velocity was moved at a rate of 3-4 cm/sec. Baseline temperatures were taken two minutes prior to treatment via implantable thermocouples 1.6 cm below the tissue surface. During treatment, intramuscular tissue temperatures were recorded every 20 seconds. However, treatment was terminated if patients felt discomfort. In the Omnisound group, every participant opted to discontinue participation at an average of six minutes into the treatment duration due to discomfort.

Every treatment using the Excel Ultra III and Dynatron units lasted the full 10-minute duration. The average tissue temperature of the Omnisound unit treatments at termination was 41°C, averaging around a 6°C increase from baseline. This was significantly ( $P = .001$ ) greater than the changes observed in the Excel Ultra III and Dynatron units, which failed to achieve final intramuscular temperatures of 40°C across all 10-minute treatments. Both units averaged around 3-4°C tissue temperature increase from baseline, with no significant differences between the two units. These results suggest the Omnisound 3000C™ can produce greater heating than the Excel Envy III (61% Omnisound heating capability) unit and the Dynatron 950 (59% Omnisound heating capability) unit.

There is a concern over the methodology of Merrick's analysis because researchers treated an area two times the transducer head rather than two times the measured ERA. The justification for this methodology was that often clinicians select US treatment area based off transducer surface area rather than true ERA.<sup>30,32</sup> Additionally, when comparing results of Merrick et al<sup>32</sup> with Draper et al,<sup>5</sup> there are observable differences in heating rates of the

Omnisound 3000C™ at 3 MHz, 1.5 W/cm<sup>2</sup>. Draper reported heating increases of 0.9°C/min. Applying this rate to a six-minute treatment with an Omnisound 3000C™ unit would produce a final temperature of 5.4°C above baseline. Merrick et al<sup>32</sup> reported average differences of 6°C. Additionally, Holcomb and Joyce<sup>31</sup> observed an average of 5.81°C increase with a 10-minute Omnisound 3000C™ US treatment. However, the intensity used was 1.0 W/cm<sup>2</sup>, which should produce a lower rate of heating. Based off the findings of the Merrick et al<sup>32</sup> study, as well as comparing it to similar studies,<sup>5,31</sup> differences exist between US brand units, as well as within the Omnisound brand itself. Understanding differences between units will allow clinicians to accurately apply therapeutic US in practice.

In attempts to reveal underlying reasons for heating differences between US units, researchers have also considered variables such as the ERA and SAI of US transducers as an area of interest. Following the research by Holcomb and Joyce,<sup>31</sup> Straub et al<sup>34</sup> examined the ERAs and calculated normalized SAI (nSAI) for 66 total transducers from different manufacturers, including 11 new Omnisound transducers. While other manufacturers measure a certain number of transducers and then clear all of those produced, Omnisound measures and reports the ERA for all produced transducers.<sup>30,34</sup> Researchers calculated Omnisound nSAI by taking a ratio of the measured output power (at 1 MHz frequency, 1.0 W/cm<sup>2</sup> intensity) of the transducer at 5 W and then measured ERA, and then multiplied it by the ratio of the Omnisound reported ERA and a standardized ERA of 5.0 cm<sup>2</sup>.

The authors<sup>34</sup> reported nine of the Omnisound transducers had measured ERAs that coincided with their reported values, while two of the transducers had 1.7 cm<sup>2</sup> and 2.2 cm<sup>2</sup> increases in ERA when measured compared to their reported values. For nSAI, the Omnisound transducers had the second lowest group value ( $0.88 \pm 0.05$  W/cm<sup>2</sup>) in front of Dynatron

transducers ( $0.84 \pm 0.05 \text{ W/cm}^2$ ). However, the low nSAI values of Omnisound transducers occurred due to the manufacturer reporting lower than measured ERAs of the two transducers, in turn decreasing the mean of the cohort. The two Omnisound transducers mentioned had the lowest nSAIs ( $0.57 \text{ W/cm}^2$  and  $0.60 \text{ W/cm}^2$ ) of all 66 transducers examined in this study. This also resulted in Omnisound having the largest nSAI variability (53%) compared to all other manufacturers. Researchers were unsure as to why such large differences in the two transducers existed, due to Omnisound measuring and reporting the specific ERA of each transducer at both frequencies. Regardless of manufacturer, continuing to produce accurate measures of ERA and SAI are crucial for consistent and accurate US application, and additional research on differences in transducer measured versus manufacture reported ERA values is needed.

Continuing transducer examination, Demchak et al<sup>37</sup> also directly compared three Omnisound 3000 US transducers, identified as transducers A, B, and C. All transducers had an ERA of  $4.4 \text{ cm}^2$ , transducer A had a BNR 2.4:1, while B and C had BNRs of 2.7:1. In a 10 minute, 1 MHz,  $1.2 \text{ W/cm}^2$  treatment; no significant differences existed between the end intramuscular (3 cm deep) temperatures produced by the US from each transducer. The heating rates of the transducers also mirrored the heating rates of Draper et al.<sup>5,37</sup> However, the intramuscular temperature increases appeared curvilinear in nature compared to the linear rates described by Draper et al.<sup>6</sup> Transducer C hit the goal tissue temperature of  $2.5^\circ\text{C}$  four minutes faster than the other two transducers, and thus provided moderate heating for a longer period.<sup>37</sup> Variability may exist in areas not explained by differences in ERA or BNR, such as unpredictable heating dispersion potentially caused by the hottest area of the US field consistently running over the thermocouple. Demchak et al<sup>37</sup> suggested future research of US heating may require additional thermocouples in the treatment area to fully describe the heating

process and minimize unpredictable heating dispersion. Furthermore, they hypothesized moving the transducer in small overlapping circles within the treatment area may not allow areas of high intensity to be adequately dispersed. It is important future researchers are made aware of these potential methodological concerns to attempt to combat them.

### **2.6.3. Other Ultrasound Brands**

Researchers are becoming increasingly interested in examining US units, apart from the Omnisound, and comparing them to the known literature and modality textbook recommendations. Researchers<sup>31,32,34</sup> have shown inconsistencies may be prevalent amongst US unit brands in terms of tissue heating rates. Defining parameters for specific US units is imperative to create accurate treatment guidelines for clinical use. However, few studies examining specific units exist.

In further examination into the US unit manufacturer Dynatronics, Gange et al<sup>35</sup> examined heating quality and depth of US penetration of the Dynatron Solaris 708 in 30 healthy participants. Intramuscular gastrocnemius temperatures were measured at 1.0, 1.75, and 2.5 cm depths, with a target tissue temperature increase of 4°C (vigorous heating). The intensity of the treatments was 1.0 W/cm<sup>2</sup> and the frequency was 3 MHz. The treatment duration was 20 minutes and the treatment would be terminated if the patient felt discomfort. The results were compared to the reported rate of heating for the Omnisound 3000™ with a treatment of the same parameters, which is 0.6°C/min (Table 1).<sup>5</sup> For the Dynatron Solaris, researchers reported a 0.70°C/min rate of heating at the 1.0 cm depth, a +0.12°C/min<sup>35</sup> compared to the Omnisound 3000™ heating rates.<sup>6,31</sup> For the depths of 1.75 and 2.5 cm, heating rates were measured to be 0.39°C/min and 0.18°C/min, respectively which was lower than the rate of 0.6°C/min of the Omnisound unit. At the depth of 2.5 cm, the rate of heating was measured to be 0.18°C/min,

indicating a 20+ minute treatment is needed to reach the target 4°C temperature.<sup>35</sup> A longer duration when compared to a suggested 7-minute treatment to reach the same 4°C increase with the Omnisound parameter guidelines (Table 1).<sup>5</sup> While the measured rate at the 1.75 cm depth by Gange et al<sup>35</sup> is consistent with a measured rate by Merrick et al<sup>32</sup> for the same depth, the unit model (Dynatron 950) and intensity (1.5 W/cm<sup>2</sup>) were different. This notable finding suggests unit models from the same manufacturer may also vary in their performance. Given the measured values, researchers suggested applying the current textbook parameters based off the Omnisound 3000<sup>6,31</sup> to the Dynatron Solaris 708 would not reach the target tissue temperature of 4°C at depths greater than 1.0 cm.<sup>35</sup>

Apart from the US unit itself, there has been an increasing interest in differences between US transducers produced from various manufacturers. In the aforementioned research by Straub et al,<sup>34</sup> the nSAI and ERAs of 66 total transducers from different manufacturers (Chattanooga, Dynatronics, Mettler, Omnisound, Rich-Mar, and XLTEK) were calculated and compared to the values given from the respective manufacturer. For each transducer, the ERA was calculated via the use of a hydrophone to measure output (in voltage). To determine the ERA, conversions and calculations were used to obtain the area over which the intensity of the transducer was greater than 5% of the peak intensity integral. The nSAI of each transducer was calculated by taking the actual output power at a display power of 5W divided by the experimentally measured and calculated ERA. Regarding nSAI, Mettler showed the highest measured value (1.39 W/cm<sup>2</sup>), followed by Rich Mar (1.21 W/cm<sup>2</sup>), XLTEK (1.15 W/cm<sup>2</sup>), Chattanooga (1.10 W/cm<sup>2</sup>), Omnisound (0.88 W/cm<sup>2</sup>), and Dynatronics (0.84 W/cm<sup>2</sup>). Additionally, individual transducer nSAI ranged from 0.57 W/cm<sup>2</sup> (Omnisound) to 1.61 W/cm<sup>2</sup> (Mettler), with a range from the digitally reported nSAI values of -43% to +61% with the cohort of all 66 transducers. Also, intra-

manufacturer variability of nSAI ranged up to 53%. Regarding ERAs, the measured and reported values are shown in Table 3 below.

**Table 3**

*Straub et al<sup>34</sup> US Transducer Measured vs Reported ERA Values*

Manufacturer	Measured ERA (cm <sup>2</sup> )	Reported ERA (cm <sup>2</sup> )
Rich-Mar	3.83 ± .21	5.0 ± 1.0
Chattanooga	3.95 ± .23	4.0 ± 1.0
Mettler	4.01 ± .34	5.0 ± 1.0
XLTEK	4.61 ± .49	5.0 ± 0.75
Omnisound	5.05 ± .60	4.45 ± 0.67*
Dynatronics	5.35 ± .28	5.0 ± 1.0

\* Omnisound reports ERAs for each individual transducer.

When comparing ERAs, it is important to consider the reported value by the manufacturer in addition to comparing between manufactures. For example, Chattanooga transducers' measured ERA value of 3.95 ± .23 cm<sup>2</sup> is much closer to the reported value of 4.0 ± 1.0<sup>2</sup> than Mettler transducers' values of 4.01 ± .34 cm<sup>2</sup> measured and 5.0 ± 1.0 cm<sup>2</sup> reported. Overall, the researchers showed concern over the inaccurate statements of ERA, which in turn cause large variability within SAI of transducers. Manufacturers must take more care in reporting proper ERA values, and measures of all output variables are vital in determining clinical effectiveness as well as producing accurate research regarding therapeutic US.

Another popular US manufacturer examined by researchers is Rich-Mar. Using a Rich-Mar Theratouch 7.7 US unit, Hayes et al<sup>26</sup> performed 1.5 W/cm<sup>2</sup>, 10-minute, US treatments at 1 and 3 MHz, and observed differences compared to the Omnisound<sup>5</sup> heating rates. The Theratouch 7.7 used in the study had a manufacturer reported ERA of 5 cm<sup>2</sup> and BNR of 5.5:1. However, the researchers concluded the crystal ERA must be smaller than 5 cm<sup>2</sup> since the transducer face was also 5 cm<sup>2</sup>. Treatments were performed over an area twice the size of the

transducer face on the medial calf. The researchers measured Theratouch heating rates with a 3 MHz treatment at a depth of 2.5 cm and reported the rate of temperature change to be 1.19°C/min, faster than the measured Omnisound rate of 0.9°C/min<sup>5</sup>. However, the 1 MHz Theratouch heating rates were measured to be 0.13°C/min, slower than the measured Omnisound rate of 0.3°C/min<sup>5</sup>. Additionally, these results contrast the differences between 1 MHz and 3 MHz reported by Draper et al<sup>5</sup>, where the suggested rate of heating increase between the two frequencies is three-fold. Hayes et al<sup>26</sup> observed the difference between 1 MHz (0.13°C/min) and 3 MHz (1.19°C/min) to be over nine-times greater. These comparisons further emphasize the existing difference between US unit brands.

Other manufacturers such as Chattanooga have units which frequently appear in physiotherapy clinics,<sup>13</sup> but are under researched in terms of heating capability. Holcomb and Joyce<sup>31</sup> measured the mean intramuscular heating rates of each treatment to be 0.58°C/min for the Omnisound 3000 and 0.39°C/min for the Forte 400 Combo over 10 total treatments. These results suggested the Omnisound 3000 is more effective at heating tissue at a 1.2 cm depth compared to the Forte 400 Combo unit. While the heating capability of the Omnisound 3000 unit used in this study aligned with textbook recommendations,<sup>5,16,18</sup> applying the textbook parameters to the Forte 400 Combo would produce different intramuscular temperatures than suggested, potentially disrupting treatment goals.

Regarding more modern Chattanooga units, Demmink et al<sup>36</sup> explored the depth of penetration of thermal US using a Chattanooga Intelect XT<sup>®</sup>. The study was not performed *in vivo*, it was conducted on 3 samples of muscle tissue from a pig cadaver. The transducer ERA was reported by the manufacturer as 5 cm<sup>2</sup>, and no BNR was reported. Ultrasound was applied at frequencies of 0.86 MHz, 2 MHz, and 3 MHz, with an intensity of 2.0 W/cm<sup>2</sup>, using a 5 cm



transducer. Thermal imaging was used rather than thermocouples to record tissue temperature; the researchers did not report the heating detection capabilities of thermal imaging in terms of maximal depth. Treatments were applied either statically, with the transducer fixed in place over the treatment area, or dynamically, during which the transducer was moved in a circular fashion at a rate of 2 cm/sec over an area twice the size of the transducer ERA (reported at 5 cm<sup>2</sup>). Both treatments lasted for six minutes. The results were reported as heating depth ratios; given by comparing the deepest point in a temperature range of the 0.86 MHz and 2 MHz treatments taken over the deepest point temperature in a temperature range of the 3 MHz treatment. The temperature contour reporting ranges were: 1-2°C, 2-4°C, and 4-8°C. For example, the depth from the transducer to the deepest point of the 1-2°C increase range for a 2 MHz treatment was divided by the deepest point for the corresponding range of a 3 MHz treatment, and reported as a ratio. Therefore, it is unclear how deep each treatment penetrated, and to what extent the temperatures reached in terms of depth.

After treatment comparison, no significant differences were found in heating depths for both forms of application across each tissue sample. However, ratios for the 2 MHz dynamic treatments ranged from 1.06 to 0.68 over the temperature ranges, with 5 of 6 data points falling below a 1.0 ratio. These findings indicated 2 MHz treatments did not penetrate as deep as 3 MHz in all but one recorded temperature range (1-2°C) from one tissue sample. Results from these treatments, despite the nature of the test tissue, may contradict previous studies by Draper<sup>5</sup> because no significant differences were noted between frequency groups. However, it is important to acknowledge the discrepancy between animal cadaver and *in vivo* analysis as deceased tissue lacks the thermoregulatory mechanism of blood circulation, and therapeutic US will always clinically be applied to living tissue.

Recently, an unpublished examination of the heating capability of a Chattanooga Intellect Legend XT<sup>®</sup> was conducted on human participants by Smith et al.<sup>42</sup> Twenty-five volunteers received a 3 MHz, 1.0 W/cm<sup>2</sup>, 15-minute thermal US treatment over their medial gastrocnemius muscle. Heating data was obtained via thermocouples inserted at depths of 1.0, 1.75, and 2.5 cm depths below tissue surface. The US treatment was applied in a template twice the size of the manufacturer reported ERA and a metronome was utilized to maintain a 4 cm/s transducer velocity. Baseline temperatures were obtained, and temperature changes were recorded via an Iso Thermex throughout the treatment duration. The mean baseline temperature for the 1.0 cm depth was 33.88°C ± 1.14 and increased 4.10°C after 6 minutes at a rate of 0.68°C/min. At the 1.75 cm depth, the baseline temperature was 34.58°C ± 0.94 and increased 4.17°C after 8 minutes at a rate of 0.52°C/min. And at the 2.5 cm depth, the mean baseline temperature was 34.55°C ± 1.28 and increased at a rate of 0.20°C/min and thus did not reach a 4°C increase within the treatment duration. Based on these rates, a 6 to 20-minute US treatment may be required to increase tissue temperature 4°C dependent on the tissue depth. This timeframe and the associated heating rates differ from those seen in modality textbooks<sup>16,18,33</sup> based off Draper et al,<sup>5,27</sup> emphasizing the problem of current guidelines in the teaching of and clinical application for therapeutic US.

While thorough understanding of several different manufacturer US units would be ideal, emphasis can be made to the Chattanooga brand due to its reported popularity among clinicians.<sup>13</sup> Outside of Holcomb and Joyce,<sup>31</sup> who examined an older Chattanooga unit, and Demmink et al,<sup>36</sup> in which US analysis was performed on animal cadaver tissue, no other published research exists on the Chattanooga manufacturer's popular units. Based on the available literature, it is suggested variability exists both within and between US manufacturers in terms tissue heating capability.<sup>29-32,34,35,42</sup> To establish claims about the effectiveness of

therapeutic US as a rehabilitative modality, researchers must first be certain intramuscular tissue is being heated to the level of proposed effects. Conducting quality US research is dependent on understanding heating characteristics of various US units, starting with the most popular manufacturers, such as Chattanooga. Currently, modality textbooks<sup>16,18,33</sup> only provide recommendations based off research pertaining to a single US unit and manufacture. Educators, clinicians, and athletic training organizations must recognize this in constructing appropriate resources and certification tests for current and future ATs.

## **CHAPTER III. METHODOLOGY AND PROCEDURES**

### **3.1. Purpose of the Study**

The purpose of this study was to examine the commonly used brands and models of US units used by ATs currently practicing clinically, as well as inquire about common US parameters ATs use to treat common conditions and pathology. Information regarding the most used US units and parameters by ATs doesn't exist in the literature. This data was collected with the intended use of guiding future research of therapeutic US in the field of Athletic Training. The research questions guiding this study included: 1.) What brands and models of therapeutic US units are most commonly available for use by clinical ATs? 2.) What brands of therapeutic US units are most used by clinical ATs? 3.) What are the most common thermal US parameters used by ATs clinically?

### **3.2. Experimental Design**

This study was a cross-sectional survey design analyzing clinical ATs conducted via digital questionnaire. Administration of the questionnaire was through the NATA data collection service program.

### **3.3. Participants**

A random sample of 1000 ATs currently active as a clinician were recruited for survey via the use of the NATA data collection service program. To participate in the questionnaire, participants were certified as an AT by the Board of Certification (BOC®), a registered member of the NATA, and currently practicing in a clinical setting as an AT.

### **3.4. Instruments for Data Collection**

In this study, an electronic survey was used to measure the following direct constructs: common pathologies treated with therapeutic US, common manufacturer brands and models of

US units available to ATs, common manufacturer brands and models of US units frequently used by ATs, and common clinical parameters cited by ATs for thermal US treatments. Additional information regarding years of experience as an AT and population demographics was also collected. No published literature is available surveying manufacturer US unit availability and use by practicing ATs. The questionnaire was developed by the investigators and contained closed ended questions to measure survey constructs. Questionnaire administration and data collection was conducted through the NATA Qualtrics data collection platform. The non-identifiable data was collected over the span of four weeks and stored on the NATA Qualtrics platform for 90 days upon completion, after which all data sets were destroyed. A data summary sheet is currently secured in a NATA digital file for seven years.

### **3.5. Procedures**

Prior to questionnaire administration, the study was approved by the North Dakota State Institutional Review Board. The questionnaire provided in this study was developed by the principal and co-investigators. A research survey request application form, the IRB application and approval forms, an informed consent document, an invitation email, the NATA research survey service agreement form, and the questionnaire itself was submitted to the NATA data collection service program for approval. After approval, the recruitment email, consent form, and survey were administered to 1000 clinically active ATs via the developed recruitment email sent from NATA. Participants had four weeks to respond to the questionnaire, and a reminder email was sent to participants two weeks after the initial questionnaire was sent. Data was collected and stored via the NATA Qualtrics platform for 90 days upon completion of the 4-week response period. The investigators had access and ownership rights to all responses collected. Data was exported from Qualtrics where it was securely stored digitally on the NDSU one drive for

analysis. A summary data sheet will be stored in a secured NATA digital file for seven years following the 90-day storage period.

### **3.6. Statistical Analysis**

SPSS statistics software was used to determine descriptive statistics, central tendency data, and frequencies of most common US manufacturer brand and model, most common treatment goal, number of US units available in the workspace, most common thermal US parameters used by ATs, years of athletic training experience, and general demographic information. Independent t-tests were performed to examine differences in parameter selection between ATs based on years of clinical experience.

## CHAPTER IV. MANUSCRIPT

### 4.1. Abstract

[Study Design] Digital Survey

[Background] Identifying commonly used ultrasound (US) machine brands, unit models, and treatment parameters will assist athletic trainers (ATs) in accurately developing future guidelines for thermal US use.

[Objectives] The purpose of this study was to examine common US unit manufacturer brands and parameters used by ATs in their workplace.

[Methods] One thousand ATs were randomly selected and sent a digital survey via the NATA. Participants were certified as an ATC, a registered member of the National Athletic Trainers' Association (NATA), and currently practicing as an AT. The survey inquired about the experience and type of clinical setting ATs had, the US brand/model availability at their clinical site, specific US parameters they use, and the conditions they use US to treat.

[Results] Response rate of the survey was 0.023% (23 respondents). Overall, Chattanooga brand was cited as the most commonly available (n=17), followed by Dynatronics (n=8), Rich Mar (n=6), Mettler (n=1), and Excell (n=1), no respondents claimed to have Omnisound, XLTEK, or Enraf-Nonius. The most commonly observed model was Chattanooga Intellect Legend XT (n=11), followed by Rich Mar Theratouch (n=4), Rich Mar Autosound 8.5 (n=3), Chattanooga Vectra Genisys (n=3), Dynatronics Solaris (n=2), Dynatronics 950 (n=1), Rich Mar EVO (n=1), and Rich Mar TM3p (n=1). For the three general parameters threshold questions based on the current modality textbook guidelines for US, participants reached 1 and 2°C thresholds, but failed to achieve the 4°C with their reported parameters.

[Conclusions] Overall, ATCs had many brands/models available at their clinical sites. When comparing the reported parameters to the heating rates reported in the literature, participant parameters would often not accurately achieve the appropriate tissue temperatures. Continuing to learn more about common brands and models of US units, as well as clinician selected treatment parameters, will assist future researchers and ATs in proper US application.

[Level of Evidence] Level 4

[Key Words] Therapeutic ultrasound, unit, treatment, parameters

## 4.2. Introduction

Therapeutic Ultrasound (US) has remained a modality used clinically by ATs over the last half century.<sup>3,7,11,13</sup> Clinicians often select thermal US as a therapeutic modality for treatment of tissue inflammation, reduction of pain and swelling, and increase of tissue extensibility.<sup>11</sup> These benefits are achieved via heating the target tissue to a certain temperature threshold.<sup>16,18</sup> A temperature increase of 1°C, mild heating, is obtained for treatment of minor inflammation or to accelerate the metabolic rate and the total healing process.<sup>16,18</sup> Increasing tissue temperature 2-3°C, moderate heating, is used to treat muscle spasm, decrease pain, increase blood flow, and reduce chronic inflammation.<sup>16,18</sup> Heating to 4°C or greater, vigorous heating, allows for increased tissue extensibility, reduction of scar tissue, and inhibition of sympathetic activity.<sup>16,18</sup>

Inputting appropriate parameters into the US unit is vital for the clinician to safely and accurately heat target tissue. These parameters include US frequency (MHz), intensity (W/cm<sup>2</sup>), and treatment duration (minutes). Parameter selection guidelines are frequently taught to ATs based off research conducted by Draper et al<sup>18</sup> who established heating rates commonly seen in therapeutic modality textbooks.<sup>16,18</sup> In more recent years, researchers such as Merrick et al,<sup>32</sup> Gange et al,<sup>35</sup> and Smith et al<sup>42</sup> have found discrepancies between the temperatures produced by



different manufacturers and the guidelines provided by Draper et al<sup>18</sup> and therapeutic modality textbooks. The different US units rarely have reinforced the commonly taught guidelines. No literature exists surveying ATs about their commonly inputted US parameter selection, and whether these parameters adhere to current guidelines for parameter selection.

Current textbook parameters are from the 1995 Draper et al<sup>18</sup> research with an Omnisound brand US unit. However, there are now a variety of different US brands and unit models available for clinical use. Therapeutic US units have been produced by a multitude of different manufacturers, including: Accelerated Care Inc. (Topeka, KS), Mettler Electronics (Anaheim, CA), Chattanooga Corp. (Chattanooga, TN), Dynatronics (Salt Lake City, UT), Rich-Mar (Inola, OK), Power Technologies Inc. (Schenectady, NY), Mid-Canada Medical (Ontario, Canada), Excel (Ontario, Canada), Bosch (Broadview, IL), Amrex (Carson, CA), and Enraf-Nonius (Rontgenweg, Netherlands). Outside of one research study focusing on calibration of US units,<sup>13</sup> no other published research exists concerning the availability of any given brand or model of US unit in athletic training facilities or clinics. More information needs to be known about the brands and models of US units available for clinical use amongst ATs, as well as ATs' commonly inputted US parameters for thermal treatments. Acquisition of this information may be incredibly beneficial for future research on US heating capabilities and increasingly detailed US parameter guidelines for future clinicians.

### **4.3. Methods**

#### **4.3.1. Participants**

One thousand certified ATs were contacted for participation via email through the NATA research survey center. Participants were required to be certified as an ATC by the Board of Certification (BOC®), a registered member of NATA, as well as actively practicing as a

clinician. Exclusion criteria included any participants not currently certified by the BOC or actively clinically practicing. Informed consent for participation was granted via completion of the questionnaire.

#### **4.3.2. Procedures**

Prior to the start of the collection period, the university's institutional review board approved this research study. Athletic trainers who received the email and agreed to complete the questionnaire were directed via hyperlink to the NATA's Qualtrics data collection platform where they were prompted through a 15-question survey (Appendix A). The principal and co-investigator constructed the survey and sent it to two additional experts to ensure construct and content validity prior to submission to the NATA. The first five items on the questionnaire inquired about athletic training experience, setting, and access to therapeutic US at their workplace. Questions six through eleven asked about specific US brand and model unit availability in the participant's workplace, as well as the participant's general US usage. Questions twelve through fifteen required participants to input the thermal US parameters (frequency, intensity, and treatment duration) they would use to heat tissue to either a 1, 2, or 4°C increase, as well as the conditions participants would treat with therapeutic US. The temperature thresholds in these questions are based on how current modality textbooks define mild, moderate, and vigorous heating.<sup>16,18</sup> If participants indicated they are not currently practicing as an ATC, the survey terminated.

#### **4.3.3. Statistical Analysis**

Demographic information for AT experience, clinical setting, and general US availability was collected. Measures of central tendency were used to determine the most prevalent US brand and model unit available used by practicing ATs, as well as average parameters given by

participants in response to temperature threshold questions. Independent t-tests were conducted to compare US parameters between ATs with less experience (1-9 years) and those with more experience (10+ years). Statistical significance for all statistical analyses was set at a *P* value of < 0.05. All statistical analysis was completed via SPSS statistics software version 25.0 (IBM®, Armony, New York), or via Microsoft Excel® (Microsoft Corporation®, Redmond, Washington)

#### **4.4. Results**

Twenty-seven participants responded to the questionnaire, with twenty-five eligible for inclusion in the study. Two participants were not practicing clinically at the time of the survey and therefore removed. Participants widely ranged in terms of athletic training experience, with most of the respondents working clinically in the NCAA Division 1 setting. Demographic data is summarized in Table 4.

**Table 4***Demographic Data Summary*

Categorical Variables			Continuous Variables		
Active Clinician	Yes	23	Years ATC	Mean (SD)	12.5 (10.6)
	No	2		Min	1
Clinical Setting	NCAA D1	12		Max	46
	NCAA D2	3		Median	9
	NCAA D3	1			
	NAIA	1			
	Professional / Semi Professional	2			
	Sports Org.				
	Performing Arts High School	1 1			

Participants reported a high access to therapeutic US machines at their clinical sites. Most respondents use therapeutic US at their workplaces, with varying levels of frequency of use. Responding clinicians used therapeutic US for the treatment of a variety of conditions, the top three included: scar tissue reduction, chronic strains, and chronic sprains. In terms of US unit variety, many participants had several US units available at their clinical site, with numerous respondents having different brands and models of units for use. Overall, Chattanooga was cited by participants as the most commonly available brand for US units (n=17), followed by Dynatronics (n=8), Rich Mar (n=6), Mettler (n=1), and Excell (n=1), no respondents claimed to have Omnisound, XLTEK, or Enraf-Nonius. General US usage information and brand and model US unit availability data are summarized in Table 5 and Table 6, respectively.

**Table 5***Summary of General Ultrasound Usage*

Access to US in workplace	Yes	20	Do you actively use	Yes	14
	No	1		No	6
# US treatments performed in the average week	0 - 3	7			
	3 - 5	4			
	5 - 7	1			
	7 - 10	3			
	> 10	1			
Conditions / Pathologies	# Clinicians who use US in treatment of				
Scar Tissue Reduction	11				
Chronic Strain	10				
Chronic Sprain	9				
Muscle Spasm	9				
Tissue Extensibility	9				
Contusion	5				
Hematoma	4				
Acute Sprain	2				
Acute Strain	2				
Acute Post-Surgical	1				
Bursitis	1				

**Table 6***Ultrasound Brand and Model Information*

US units available	Mean (SD)	3.4		
	Min	1		
	Max	10		
US Manufacturer Brands Information		US Unit Model Information		
Brand Name	# Sites with brand	Unit Model Name	# of units	
Chattanooga	17 (8)	Chattanooga Intelect	11	
Dynatronics	8 (1)	Rich Mar Theratouch	4	
Rich Mar	6 (2)	Rich Mar Autosound 8.5	3	
Mettler	1	Chattanooga Vectra	3	
Excell	1	Dynatronics Solaris	2	
		Dynatronics 950	1	
		Rich Mar EVO	1	
		Rich Mar TM3P	1	

\* Only included respondents who had US units available.

Thermal US parameters suggested by respondents varied for each temperature threshold inquired (1, 2, and 4°C). The reported parameters were divided into two groups at each temperature threshold based on the frequency (1 MHz or 3 MHz), as these are the two frequencies available for selection on modern US units. Participants often selected 1 MHz over 3 MHz for frequency selection. Descriptive statistics were gathered for each frequency group over the three temperature levels. Respondent parameter summary information is presented in Table 7. Two participants were excluded from analysis pertaining to the 4°C-temperature threshold question. One failed to report a frequency and another responded with a 2 MHz frequency. This participant's data was excluded as 2 MHz frequency is not the focus of this study.

**Table 7**

*Parameter Summary for 1, 2, and 4°C Thresholds*

1°C Summary				
	3 MHz Group (n=7)		1 MHz Group (n=10)	
	Mean (SD)	Median	Mean (SD)	Median
Intensity (W/cm <sup>2</sup> )	1.18 (0.52)	1.50	1.04 (0.20)	1.00
Duration (Min)	4.86 (1.57)	5.00	6.36 (1.32)	6.00
2°C Summary				
	3 MHz Group (n=4)		1 MHz Group (n=13)	
	Mean (SD)	Median	Mean (SD)	Median
Intensity (W/cm <sup>2</sup> )	1.25 (0.82)	1.45	1.38 (0.28)	1.20
Duration (Min)	5.38 (1.97)	5.75	8.30 (1.90)	7.00
4°C Summary				
	3 MHz Group (n=4)		1 MHz Group (n=11)	
	Mean (SD)	Median	Mean (SD)	Median
Intensity (W/cm <sup>2</sup> )	1.56 (0.43)	1.63	1.72 (0.34)	1.50
Duration (Min)	6.00 (1.83)	6.00	8.90 (3.29)	3.29

Independent t-tests were used to compare parameters given for the three thresholds between less experienced clinicians (n=10, 1-9 years AT experience) and more experienced

clinicians (n=8, 10+ years AT experience). This was accomplished again by first dividing the participants into frequency groups (1 MHz or 3 MHz), and then comparing the more and less experienced groups by frequency for each temperature threshold. Participants who failed to submit all information required for each question were excluded from analysis. No significant differences existed between 1°C groups for either intensity or time: 3 MHz intensity ( $P = 0.75$ ), 3 MHz duration ( $P = 0.09$ ), 1 MHz intensity ( $P = 0.43$ ), and 1 MHz duration ( $P = 0.63$ ). For the 2°C threshold comparisons, none of the more experienced clinicians selected 3 MHz as their frequency of choice to reach the target temperature. No significant differences were noted for the 1 MHz 2°C threshold in intensity ( $P = 0.15$ ) or duration ( $P = 0.42$ ). Similarly, to 2°C, no participants from the experienced group selected 3 MHz frequency as their choice to reach 4°C. No significant differences were recorded between the groups for 1 MHz intensity ( $P = 0.60$ ) or duration ( $P = 0.53$ ). Summary of the comparative analysis between lesser and more experienced clinicians is in Table 8.

**Table 8***Parameter Comparison between Less Experienced (LE) and More Experienced (ME) Clinicians*

1°C Summary			
LE 3 MHz Group (n=4)		ME 3 MHz Group (n=3)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.25 (0.33)	1.33 (0.29)	0.75
Duration (Min)	4.00 (1.41)	6.00 (1)	0.09
LE 1 MHz Group (n=6)		ME 1 MHz Group (n=5)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.00 (0.13)	1.10 (0.26)	0.43
Duration (Min)	6.17 (1.33)	6.60 (1.52)	0.63
2°C Summary			
LE 3 MHz Group (n=4)		ME 3 MHz Group (n=0)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.25 (0.82)	n/a	n/a
Duration (Min)	5.38 (1.97)	n/a	n/a
LE 1 MHz Group (n=6)		ME 1 MHz Group (n=7)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.27 (0.20)	1.53 (0.37)	0.15
Duration (Min)	8.2 (1.64)	7.30 (2.14)	0.42
4°C Summary			
LE 3 MHz Group (n=4)		ME 3 MHz Group (n=0)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.56 (0.43)	n/a	n/a
Duration (Min)	6.00 (1.83)	n/a	n/a
LE 1 MHz Group (n=4)		ME 1 MHz Group (n=7)	
	Mean (SD)	Mean (SD)	P value
Intensity (W/cm <sup>2</sup> )	1.60 (.27)	1.79 (0.63)	0.60
Duration (Min)	10.30 (3.95)	8.86 (3.08)	0.53



## 4.5. Discussion

Accurately increasing tissue temperature to certain thresholds is critical for effective therapeutic US treatments. A temperature increase of 1°C, also known as mild heating, is utilized for treatment of minor inflammation or to accelerate the metabolic rate and total healing process.<sup>16,18</sup> Continuing tissue temperature increase to 2-3°C, or moderate heating, is accomplished to treat muscle spasms, decrease pain, increase blood flow, and reduce chronic inflammation.<sup>16,18</sup> Finally, ultrasonic heating to 4°C or greater, vigorous heating, allows for increased tissue extensibility, reduction of scar tissue, and inhibition of sympathetic activity.<sup>16,18</sup> Obtaining these temperature increases from baseline hinges upon the clinician inputting the correct frequency, intensity, and treatment duration to heat tissues accordingly. Therapeutic modality textbook heating rates<sup>16,18,33</sup> commonly taught to ATs are derived from findings by Draper et al<sup>3,5</sup> and their studies with the Omnisound 3000™ unit. However, research has shown that the heating capabilities differ amongst brands and models of US units,<sup>29-32,34,35,42</sup> which has been shown to be problematic when attempting to apply one set of parameter guidelines to all US units.

### 4.5.1. Ultrasound Brand and Model Availability

Prior to our study, the availability of different brands and models of US units specifically at athletic training clinical sites has not been researched. Our results (Table 6) indicated the Chattanooga Corp. (Chattanooga, TN) brand units were available at the greatest number of clinical sites (n=17), with eight respondents claiming it is the only brand of US unit available. The second most available unit was Dynatronics (Salt Lake City, UT), reported available at eight clinical sites, with one respondent claiming it being the only brand available at their clinical sites. While this was a nationwide survey, Artho et al<sup>13</sup> collected information on the brand and

model of calibrated US units used at Texas physiotherapy clinics which also showed the Chattanooga Corp. units being the most available unit calibrated (n=32), followed by Enraf-Nonius (Rontgenweg, Netherlands) (n=15), Rich-mar (Inola, OK) (n=11), and Dynatronics (n=10). Our survey showed no clinicians having Enraf-Nonius units available and six clinicians having Rich-mar units available. The most popular unit observed in our results was the Chattanooga Intellect Legend, with 11 units being reported available at clinical workplaces. Arto et al<sup>13</sup> observed only five of these units, however, their study was from 2002 and not targeted specifically at ATs but rather general physiotherapy clinics.

The origins of clinical parameter guidelines for US stem back to research by Draper et al<sup>1,2,5,12</sup> with the Omnisound 3000™ US unit. The findings from these studies are still used today in modern therapeutic modalities textbooks<sup>16,18,33</sup> for the education of new clinicians in clinical US application. Since then, comparison to Draper's findings and the Omnisound brand have been common in US literature. Researchers including Demchak et al,<sup>33,37</sup> Merrick et al,<sup>32</sup> Hayes et al,<sup>26</sup> Chan et al,<sup>38</sup> Straub et al,<sup>34</sup> and Gange et al<sup>35</sup> have all compared findings from their research with various other US brands to the results of Draper et al's research or manufacturer reported information of Omnisound units. Despite the importance of the Omnisound brand in the formations of modern US parameter guidelines, our study reported no Omnisound units available at the 25 clinical site locations of respondents. While this study only represents 25 athletic training clinical sites in the United States, it is an observation which warrants further investigation from researchers to determine if this is a truly a trend nationwide.

#### **4.5.2. Common Clinical Parameters**

Participants in the study were asked to give clinical parameters they would input to reach a certain temperature threshold of either 1°C, 2°C, or  $\geq 4^\circ\text{C}$  above the baseline tissue temperature.

The responses for each question were divided into groups by frequency, 1 MHz or 3 MHz, as these are primarily the frequencies which appear for selection on modern US units, and are the frequencies taught in athletic training modalities courses. The results reported by participants are summarized in Table 7. When making comparisons between our results and those reported by the literature, it's important to note most research<sup>3,5,32,35,42</sup> involving US unit heating occurs at intensities of either 1.0 W/cm<sup>2</sup> or 1.5 W/cm<sup>2</sup>. Because of this, opting to compare the mean intensity reported over a group was more difficult than to use a median intensity. Tissue heating is also observed to be curvilinear in nature<sup>35,37</sup> which may affect the theorized temperatures obtained by participant parameters. Our results for each surveyed temperature goal were compared to the rates observed by Draper et al<sup>3,5</sup> and still taught in modalities textbooks<sup>16,18,33</sup> (Table 1), as well as brand specific literature, if available.

#### ***4.5.2.1. 1 MHz Frequency Parameters***

Comparing 1 MHz parameters given by participants to modality textbook guidelines, the clinical parameters used by participants reached tissue temperature goals for all temperatures, except  $\geq 4^{\circ}\text{C}$ . For an increase of  $1^{\circ}\text{C}$ , the median intensity and duration of treatment reported were 1.0 W/cm<sup>2</sup> and 6 minutes (n=10). Applying these parameters to the guidelines set by Draper et al,<sup>3,5</sup> we would theoretically observe a  $\sim 1.27^{\circ}\text{C}$  increase from the 1 MHz group, which meets the  $1^{\circ}\text{C}$  increase goal. For an increase of  $2^{\circ}\text{C}$ , the median intensity and duration of treatment reported by participants were 1.2 W/cm<sup>2</sup> and 7 minutes (n=13). Demchak et al<sup>33</sup> reported the heating rate with an Omnisound 3000™ US unit to be  $0.32^{\circ}\text{C}/\text{min}$  at a frequency of 1 MHz and an intensity of 1.2 W/cm<sup>2</sup>. Applying this rate to the 1 MHz group yields a theorized temperature increase of  $\sim 2.6^{\circ}\text{C}$ , again meeting the temperature goal. Lastly, for an increase of  $\geq 4^{\circ}\text{C}$ , the median intensity and duration for the 1 MHz group (n=11) were 1.5 W/cm<sup>2</sup> and 8.5

minutes. Applying these parameters to textbook cited heating rates would theoretically yield a  $\sim 2.7^{\circ}\text{C}$  increase from the 1 MHz group, with a theorized additional 5 minutes of treatment time (13.5-minute total) needed to reach the  $4^{\circ}\text{C}$  increase. Overall, 1 MHz responders' parameters were accurate for heating to levels of 1 and  $2^{\circ}\text{C}$  based on textbook heating rates but failed to achieve a  $4^{\circ}\text{C}$  increase with their parameters given. While the first two temperature thresholds were reached according to reported parameters, parameters reported which failed to obtain a tissue temperature increase of  $\geq 4^{\circ}\text{C}$  may negate desired US treatment outcomes or be a detriment to patient return to sport or function.

Aside from comparisons to Omnisound, it is important to compare parameters given by respondents to other US brands with the available research. Several respondents noted Rich Mar Theratouch units were available at their clinical site ( $n=4$ ). Research by Leonard et al<sup>44</sup> measured the heating capabilities of a Rich Mar Theratouch 7.7 US unit using a frequency of 1 MHz, intensities of 0.5, 1.0, 1.5, and  $2.0\text{ W/cm}^2$ , and a treatment duration of 10 minutes. Ultrasound treatments were performed on 19 healthy volunteers' medial calf, with inserted thermocouples (4cm deep into tissue) recording temperature changes every minute. Results showed rates of temperature increase to be  $\sim 0.11^{\circ}\text{C/min}$  for  $1.5\text{ W/cm}^2$  treatments and  $\sim 0.10^{\circ}\text{C/min}$  for  $1.0\text{ W/cm}^2$  treatments. Using these heating rates measured by Leonard et al, we can theorize temperature increases utilizing our respondent's parameters. Plugging in Leonard's heating rates to the 1 MHz parameters listed, we would theorize a  $0.59^{\circ}\text{C}$  increase for the  $1^{\circ}\text{C}$  respondent parameters ( $1.0\text{ W/cm}^2$ , 6 minutes), a  $0.70^{\circ}\text{C}$  increase for the  $2^{\circ}\text{C}$  respondent parameters ( $1.2\text{ W/cm}^2$ , 7 minutes), and a  $0.94^{\circ}\text{C}$  increase for the  $\geq 4^{\circ}\text{C}$  respondent parameters ( $1.5\text{ W/cm}^2$ , 8.5 minutes). None of the respondent parameters given met temperature goals using the heating rates observed by Leonard et al for the Rich Mar Theratouch US unit. Leonard et al reported much

lower heating rates in their study, citing potential US unit calibration issues or simply design differences between manufacturers.

#### **4.5.2.2. 3 MHz Frequency Parameters**

It is important to recall while therapeutic modality textbooks<sup>16,18,33</sup> claim 1 MHz frequency is used to penetrate deeper into tissue, research has shown 1 MHz may be less effective at heating compared to 3 MHz at the same depths.<sup>26</sup> Beginning with textbook parameters guidelines,<sup>16,18,33</sup> comparisons were also performed for participants who selected 3 MHz for their US frequency. For the 1°C level, the median intensity and duration of treatment reported were 1.5 W/cm<sup>2</sup> and 5 minutes (n=7). Applying these parameters to the guidelines set by Draper et al,<sup>3,5</sup> we would theoretically observe a ~4.50°C increase in tissue temperature from the 3 MHz group. Heating tissue beyond the desired threshold may negatively impact US treatment goals and may even damage tissue or stunt the healing process. For 2°C, the median intensity and duration of treatment reported were 1.50 W/cm<sup>2</sup> and 5.75 minutes (n=4). Applying the 3 MHz parameters to the textbook guidelines, we would theoretically observe a ~5.18°C increase in tissue temperature. This temperature falls more in line with the treatment goals of an altering tissue extensibility (≥4°C), which again is not the desired goal of a 2°C increase. Finally, for ≥4°C, the mean intensity and duration of treatment reported were 1.56 W/cm<sup>2</sup> and 6 minutes for the 3 MHz group (n=4). Plugging these parameters would theoretically yield a ~5.4°C increase in tissue temperature from the 3 MHz group. While this temperature meets the treatment goal, clinicians must be cautious as to not heat tissue to the point of causing potential damage. Overall, applying textbook heating rates to the 3 MHz participant parameters would theoretically overheat tissue potentially causing harm; however, textbook parameters are based off an Omnisound unit, whereas no participants reported an Omnisound unit at their clinical site.

While no Omnisound units were available at participants' place of practice, Chattanooga Intellect units were reported as the most widely available US unit (n=11 units reported), with the brand being reported at 17 clinical sites. In a recent unpublished thesis, Smith et al<sup>42</sup> examined a Chattanooga Intellect US unit and observed US heating rates using it on human participants. Taking the median depth used in the study (1.75cm) and the parameters of 3 MHz, 1.0 W/cm<sup>2</sup>, and a treatment duration of 15 minutes; the researchers observed a heating rate of 0.52°C/minute. Applying this heating rate to our 3 MHz participants responses (Table 7), we would theorize a 2.6°C final temperature for the 1°C increase parameters, a 2.9°C final temperature for the 2°C increase parameters, and a 3.12°C final temperature for the ≥4°C increase parameters. However, due to Smith et al<sup>42</sup> using a 1.0 W/cm<sup>2</sup> and all our 3 MHz respondents averaging a 1.5 W/cm<sup>2</sup> intensity, we would expect the theorized rates to be higher than the ones calculated. While this may move the ≥4°C parameters closer to the goal temperature, we cannot say for sure. For the other two parameter levels, 1 and 2°C, 3 MHz participants were already overheating the tissue without adjusting for an increased intensity, which may result in negative treatment outcomes such as damaging tissue or slowing the healing process. Additional research needs to be performed on the Chattanooga Intellect to accurately compile the heating rates of this US unit.

While Chattanooga brand US units was the most observed at respondent clinical sites (n=17), Dynatronics brand US units were the second most reported (n=7). In a recent study by Gange et al,<sup>35</sup> a Dynatronics Solaris unit was utilized, to heat healthy human tissue with US at a rate of 0.39 °C/min at 1.75 cm tissue depth. The parameters used by researchers in the study were 3 MHz frequency, 1.0 W/cm<sup>2</sup> intensity, and a 20-minute treatment duration. Merrick et al<sup>32</sup> observed the same heating rate (0.39 °C/min) with a different Dynatronics unit (Dynatron 950 US unit), with a frequency of 3 MHz and an intensity of 1.5 W/cm<sup>2</sup>. Comparing participants

given 3 MHz parameters (Table 7) to the heating rates found by researchers, we would theorize a final temperature increase of 1.95°C for the given 1°C parameters, a 2.2°C increase for the given 2°C parameters, and a 2.3°C for the given  $\geq 4^\circ\text{C}$  parameters. Using Dynatronics units, we can estimate clinicians accurately heating to 1 and 2°C thresholds but falling short of the crucial 4°C threshold. However, these final temperatures are only rough estimates, as Gange et al used a lower intensity and still found rates similar to Merrick et al, who used a higher intensity and a different model US unit. This further demonstrates the variation of different models in the same brand. Our comparison further indicates a need for accurately obtaining heating rates for Dyantronics brand US units with the goal of establishing appropriate parameter guidelines for clinical use.

#### ***4.5.2.3. Trends in Clinical Parameters Responses***

Finally, it is important to observe the trends of participant reported intensity and treatment time as the goal temperature threshold gradually increased from 1°C to 2°C and eventually to  $\geq 4^\circ\text{C}$ . When comparing the 1 MHz to 3 MHz group responses, reported intensities for 1°C were overall less on average in the 1 MHz than the 3 MHz group (Table 7). According to current US recommendations found in modality textbooks,<sup>18,33</sup> intensity for 1 MHz treatments should be higher than 3 MHz treatments as 3 MHz treatments heat more rapidly than 1 MHz.<sup>26</sup> Less experienced clinicians also reported a lower intensity for 1 MHz frequency treatments than 3 MHz for the 1°C threshold, and similar intensities for the 2°C and  $\geq 4^\circ\text{C}$  thresholds (Table 8). Typically, intensities for 1 MHz treatments are higher than 3 MHz treatments, as the 1 MHz frequency is typically selected for the heating of deeper tissues. Treatment times for all thresholds amongst less experienced clinicians were longer for 1 MHz compared to 3 MHz, agreeing with current textbook guidelines.<sup>18,33</sup> More experienced clinicians who selected 1 MHz

also reported a lower intensity for the 1°C compared to the 3 MHz group, which contradicts textbook recommendations. Compared to the less experienced group, the more experienced 1 MHz clinicians selected higher intensities across all three temperature thresholds, but also selected shorter treatment times compared to the less experienced group (Table 8). None of the more experienced clinicians selected 3 MHz as their choice frequency to heat 2°C or the  $\geq 4^\circ\text{C}$  thresholds. Overall, it is expected intensity and treatment times increase as the goal tissue temperature increases.<sup>18,33</sup> However, based on our responses, this trend may be worth further exploration by researchers.

A few limitations were present in this study. While many more participants started the questionnaire, only 21 eligible participants completed the survey in total. Many initial participants discontinued their participation when asked about specific models of US units available at their clinical workplace. This may be due to many ATs being away from their respective workplace due to health concerns over the COVID-19 pandemic at the time of the survey administration, and participants failing to recall specific unit models. Refining questions to be more accommodating to participants may prompt increased response. Because of a low sample size, these parameters cannot be generalized to reflect those used by all ATs. The parameters reported by respondents were initially applied to guidelines developed by Draper et al<sup>3,5</sup> and those taught in therapeutic modalities textbooks<sup>16,18,33</sup> based off an Omnisound 3000™ unit, however no Omnisound units were reported available by respondents. Theorized temperature increase may differ based on suggested variation in heating rates amongst different manufacturers.<sup>29-32,34,35,42</sup> Attempts were made to compare participant parameters to heating rates observed amongst other US brands by researchers,<sup>29-32,34,35,42</sup> however, not every brand reported available by respondents had precise parameter matches available in the literature. While no



subject in our sample reported having an Omnisound unit at their clinical site, the sample was small and doesn't represent the AT population. Based on the findings of our study, further research is needed with a greater number of subjects to fully display which US units are being used by ATs clinically. Gathering this information will be vital in guiding future clinical research with US in efforts to ensure accurate parameter guidelines are being utilized for the most observed modern US units used by ATs. While ATs will continue to use US clinically, they need to be aware of which US unit they use, and how parameters may differ from textbook recommendations.

#### **4.6. Conclusion**

The findings of our study are important to begin understanding which US brands, models, and clinical parameters are used by practicing ATs, as well as what common parameters are being used by ATs to achieve certain US heating thresholds. More information on the availability of popular brands and models of US units may aid researchers in focalizing future studies on those units observed most frequency at clinic workplaces. Based on parameters given, responding ATs may not be using thermal US effectively in clinical practice. Applying respondent parameters to the heating rates of different US units with similar parameters found throughout the literature, we observed participant parameters tended to reach the thresholds of 1 and 2°C, but almost always failed to reach the vital clinical threshold of  $\geq 4^{\circ}\text{C}$ . To provide proper care and obtain accurate treatment goals, it is vital we understand how different brands and models heat and properly apply therapeutic US. Additionally, current parameter guidelines and therapeutic modality textbooks utilize information pertaining to the Omnisound 3000 US unit, but not one of our respondents reported even having an Omnisound brand unit available at their clinical sites. Textbooks and modality education must change to accommodate the variety of US

units available from different manufacturers. This study should serve as a red flag for applying current modality textbook guidelines on US machines which are not an Omnisound 3000 US unit, as well as to demonstrate the immense need for updated parameter selection guidelines. Collecting more data on US brand availability and observing heating rates for a plethora of popular US units will be vital in the education of future clinicians, ATs or otherwise, and clinically effective and safe thermal US application.

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## APPENDIX. ULTRASOUND QUESTIONNAIRE

Q1 How many years of have you been a Certified Athletic Trainer?

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Q2 Are you currently a faculty member within a professional or post-professional athletic training education program?

Yes (1)

No (2)

Q3 Are you currently performing clinical work as an ATC?

Yes (1)

No (2)

*Skip To: End of Survey If Are you currently performing clinical work as an ATC? = No*

Q4 Please select your current clinical work setting or previous clinical work setting within the last 5 years.

- High School (1)
  - University/College - D1 (2)
  - University/College - D2 (3)
  - University/College - D3 (4)
  - University/College - NAIA (5)
  - Clinic/Rehab facility (6)
  - Professional or semi-professional sports organization (7)
  - Military (8)
  - N/A (9)
  - Other (Specify below) (10) \_\_\_\_\_
- 

Q5 Do you currently have access to therapeutic ultrasound in your clinical workplace?

- Yes (1)
- No (2)

*Skip To: Q12 If Do you currently have access to therapeutic ultrasound in your clinical workplace? = No*

---



Q6 How many ultrasound units are available in your clinical workplace?

- 0 (1)
  - 1 (2)
  - 2 (3)
  - 3 (4)
  - 4 (5)
  - 5 (6)
  - 6 (7)
  - 7 (8)
  - 8 (9)
  - 9 (10)
  - 10 (11)
  - > 10 (12)
-

Q7 What manufacturer brands of ultrasound units **are available** at your clinical workplace and how many of each?

Rich-Mar (1) \_\_\_\_\_

Chattanooga (2) \_\_\_\_\_

Mettler (3) \_\_\_\_\_

XLTEK (4) \_\_\_\_\_

Omnisound (5) \_\_\_\_\_

Dynatronics (6) \_\_\_\_\_

Enraf-Nonius (7) \_\_\_\_\_

Other #1 (Manufacturer name, number available) (8)

\_\_\_\_\_

Other #2 (Manufacturer name, number available) (9)

\_\_\_\_\_

There are no ultrasound units at my workplace. (10)

-----

Q8 Please list the specific models of ultrasound units **available** at your clinical workplace below.

Unit 1 (1) \_\_\_\_\_

Unit 2 (2) \_\_\_\_\_

Unit 3 (3) \_\_\_\_\_

Unit 4 (4) \_\_\_\_\_

Unit 5 (5) \_\_\_\_\_

Unit 6 (6) \_\_\_\_\_

Unit 7 (7) \_\_\_\_\_

Unit 8 (8) \_\_\_\_\_

Unit 9 (9) \_\_\_\_\_

Unit 10 (10) \_\_\_\_\_

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Q9 Do you currently use thermal ultrasound as a treatment for musculoskeletal injury?

Yes (1)

No (2)

---

Q10 If you answered YES to Q10, what specific models of ultrasound units do **you prefer to use most often** at your clinical workplace?

- Unit 1 (1) \_\_\_\_\_
  - Unit 2 (2) \_\_\_\_\_
  - Unit 3 (3) \_\_\_\_\_
  - Unit 4 (4) \_\_\_\_\_
  - Unit 5 (5) \_\_\_\_\_
  - Unit 6 (6) \_\_\_\_\_
  - Unit 7 (7) \_\_\_\_\_
  - Unit 8 (8) \_\_\_\_\_
  - Unit 9 (9) \_\_\_\_\_
  - Unit 10 (10) \_\_\_\_\_
- 

Q11 If you answered YES to Q9, how many total treatments of thermal ultrasound do you perform across all patients in an average work week?

- 0 - 3 (1)
  - 3 - 5 (2)
  - 5 - 7 (3)
  - 7 - 10 (4)
  - > 10 (5)
-

Q12

Current literature and modality textbooks define “mild heating” obtained from thermal ultrasound as a 1°C tissue temperature increase.

What parameters would you select to increase intramuscular tissue temperature 1°C in a 100% duty cycle ultrasound treatment?

Frequency (MHz) (1) \_\_\_\_\_

Intensity (W/cm<sup>2</sup>) (2) \_\_\_\_\_

Duration (Minutes) (3) \_\_\_\_\_

---

Q13

Current literature and modality textbooks define “moderate heating” obtained from thermal ultrasound as a 2°C tissue temperature increase.

What parameters would you select to increase intramuscular tissue temperature 2°C in a 100% duty cycle ultrasound treatment?

Frequency (MHz) (1) \_\_\_\_\_

Intensity (W/cm<sup>2</sup>) (2) \_\_\_\_\_

Duration (Minutes) (3) \_\_\_\_\_

---

Q14

Current literature and modality textbooks define “vigorous heating” obtained from thermal ultrasound as a  $\geq 4^{\circ}\text{C}$  tissue temperature increase.

What parameters would you select to increase intramuscular tissue temperature by  $4^{\circ}\text{C}$  in a 100% duty cycle ultrasound treatment?

Frequency (MHz) (1) \_\_\_\_\_

Intensity ( $\text{W}/\text{cm}^2$ ) (2) \_\_\_\_\_

Duration (Minutes) (3) \_\_\_\_\_

---

Q15

Please select the injuries/conditions for which you would include therapeutic ultrasound as part of your treatment plan. If selected, please list parameters you would use for the condition in the box below. Please include frequency, intensity, time of treatment, continuous or pulsed.

Acute Sprain (1) \_\_\_\_\_

Acute Strain (2) \_\_\_\_\_

Contusion (3) \_\_\_\_\_

Chronic Sprain (4) \_\_\_\_\_

Chronic Strain (5) \_\_\_\_\_

Muscle Spasm (6) \_\_\_\_\_

Hematoma (7) \_\_\_\_\_

Scar Tissue Reduction (8) \_\_\_\_\_

Acute Post-Surgical (9) \_\_\_\_\_

Bursitis (10) \_\_\_\_\_

Increase Tissue Extensibility (11) \_\_\_\_\_